argenx

Annual Report 2021

United in our commitment to improve the lives of patients.

At argenx, we are committed to improving the lives of people suffering from severe autoimmune diseases.

argenx

Annual Report 2021

We See You,
We Hear You,
We Are Here With You

Each day at argenx, we are motivated to pursue a better tomorrow alongside patients.

As your ally, we pioneer innovations to advance the understanding of rare diseases; we want to deliver immunology treatments to patients worldwide. We listen to patients, supporters and advocacy communities; we hear your stories and share your determination.

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 Universal Registration Document including the Annual Financial Statements 2021

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 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 made by argenx to securities and market authorities, are described in this universal registration document (the **Universal Registration Document** or **URD**).

This Universal Registration Document was prepared by argenx in accordance with Regulation (EU) 2017/1129 (as amended, the **Prospectus Regulation**) in conjunction with annex 1 and annex 2 of Commission Delegated Regulation (EU) 2019/980. This Universal Registration Document has been approved by the Dutch Authority for the Financial Markets (Stichting Autoriteit Financiële Markten, the AFM) on March 21, 2022 as competent authority pursuant to article 9 of the Prospectus Regulation. The AFM only approves this URD as meeting the standards of completeness, comprehensibility and consistency imposed by the Prospectus Regulation. Such approval should not be considered as an endorsement of the issuer that is the subject of this URD.

This Universal Registration Document is valid for a period of twelve months after its approval. The validity ends upon expiration on March 21, 2023. There is no obligation to supplement the Universal Registration Document in the event of significant new factors, material mistakes or material inaccuracies when the Universal Registration Document is no longer valid.

This Universal Registration Document may be used for the purposes of an offer to the public of securities or admission of securities to trading on a regulated market if approved by the AFM together with any amendments, if applicable, and a securities note and summary approved in accordance with the Prospectus Regulation. This Universal Registration Document also contains the information referred to in article 4 of Directive 2004/109/EG and as such – pursuant to article 9 paragraph 12 of the Prospectus Regulation – satisfies argenx's obligations to publish an annual report within the meaning of Directive 2004/109/EG.

In addition to historical information, this Universal Registration Document 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 Universal Registration Document. 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 of such terms, or by discussion of strategy. These statements relate to argenx's future results of operations and financial positions, prospects, developments, business strategies, plans and our objectives for future operations, 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 argenx only as of the dates they are made, and argenx disclaims any obligation to update forward-looking statements, except as may be otherwise required by law. The forward-looking statements in this Universal Registration Document involve known and unknown risks, uncertainties and other factors that could cause argenx's 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 chapter 2 "Risk Factors" of this Universal Registration Document.

Patient Stories

We integrate our patients aspiration into how we innovate, how we conduct research and design trials, and how we can support you in the daily struggles you face living with a rare disease.

There is a common purpose across argenx that is driven by your resilience and we welcome this opportunity to be with you on this journey.

Together we discover,
Team argenx

Patients living with a rare disease

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Together We Discover

The science of co-creation drives our quest to engineer innovative immunology solutions – but it is the resilient spirit of patients that fuels our urgency to deliver them.

Our goal is to treat the person, not just the disease, across all of our programs. We believe that through collaboration with patients and their supporters, we can create medicines that aim to address the real-life burden faced by rare disease communities.

To Our Shareholders

Contents

Tim Van Hauwermeiren

Peter Verhaeghe

"argenx will continue to work diligently to bring VYVGART to as many patients as possible around the world"

To Our Shareholders

Message from the CEO and the chairman of our Board of Directors

Dear Shareowners,

We will always remember 2021 as a pivotal moment in the history of argenx. It marked the year of our first product approval and official transition into an independent, fully integrated immunology company, owning the full value chain of a drug candidate – from identifying an immunology breakthrough to reaching patients.

We received approval of VYVGART™ (efgartigimod) from the U.S. Food and Drug Administration (***FDA***) on December 17, 2021, for the treatment of generalized myasthenia gravis (***gMG***) in adult patients who are anti-acetylcholine receptor antibody positive. On January 20, 2022, we received approval in Japan and are on track for an approval in Europe by the end of 2022. When we ventured to bring this asset into the clinic years ago, we made a commitment to the gMG community that we would deliver an innovative new treatment option to these patients who carry the daily burden of living with this serious autoimmune disease.

We are honored and humbled by the opportunity to now turn to this community and tell them we followed through on our commitment, and that we will continue to work diligently on their behalf to bring VYGART™ to as many patients as possible around the world.

The journey to arrive at our first product approvals was a feat of true co-creation, not just in 2021 but with the decade of work that led to these achievements. Efgartigimod was first built through our collaboration with Professor Sally Ward and UT Southwestern. It has now been evaluated in over 600 subjects across five autoimmune indications, and we expect to be conducting trials for ten high-value indications by the end of 2022. This will be a busy year with the start of multiple trials and plans for the readout of five registrational trials over the next four quarters, which we expect to set us up for four commercial launches in gMG, ITP, PV and CIDP by the end of 2024. It is an ambitious plan, and we're confident in our team's ability to continue to deliver across the business.

We laid out our 'argenx 2025' vision during our R&D Day last July, which outlines the growth trajectory we are on as a company driven by our differentiated pipeline candidates and growing commercial franchises in neuromuscular, hematology, dermatology and nephrology. Our goal is to be in at least 15 efgartigimod indications by 2025. We launched our first Phase 2 trial of ARGX-117 at the end of 2021, which offers a second pipeline-in-a-product opportunity across multiple franchises. And ARGX-119 was unveiled as a third high-potential candidate within our neuromuscular franchise. Through our Immunology Innovation Program, where we partner with leading disease biologists to uncover novel immunology breakthroughs, we plan to continue our pipeline expansion with the goal of adding one new asset each year.

We know that gMG is just the beginning for argenx. Our team is highly motivated, bringing strong expertise to the table, and ready to execute on our ambitious plan, and we have a strong balance sheet to support our goals, thanks to our shareholders. We want to extend our gratitude to all of our employees for their unwavering commitment to our mission of redefining immunology, our collaborators across the entire business and of course, the patients who put their trust in us to deliver.

Thank you,

Tim Van Hauwermeiren & Peter Verhaeghe

2021

In Brief

Operational Highlights

2021 was another pivotal year for argenx even through the continued challenges of the COVID-19 pandemic. We transitioned to a fully integrated immunology company following the approval of our first product, VYVGART™ for the treatment of gMG. In addition, we advanced our late-stage efgartigimod trials across four indications, announced two new efgartigimod indications and started patient trials with our second candidate, ARGX-117.

Global Efgartigimod Launch

- On December 17, 2021, the FDA approved VYVGART™ (efgartigimod alfa-fcab) for the treatment of gMG in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.
- A request for approval of 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) was submitted to the Japan Pharmaceuticals and Medical Devices Agency (PMDA), which was subsequently approved on January 20, 2022.
- Marketing Authorization and Application (MAA) of efgartigimod for the treatment of gMG was submitted and validated by the European Medicines Agency (the EMA), starting the formal review process.

Pipeline of Differentiated Antibody Candidates

- Efgartigimod (FcRn blocker)
  - Registrational trials ongoing across four serious autoimmune indications, including gMG, primary immune thrombocytopenia (**ITP**), pemphigus foliaceous (**PF**) and vulgaris (**PV**), and chronic inflammatory demyelinating polyneuropathy (**CIDP**).
  - Two additional indications announced during R&D Day: idiopathic inflammatory myopathy (**myositis**) and bullous pemphigoid (**BP**):
    - BALLAD: registrational trial of subcutaneous (SC) efgartigimod in BP initiated at end of 2021.
    - ALKIVIA: trial design finalized of SC efgartigimod in myositis following independent data monitoring committee's advice.
  - New gMG data from Phase 3 ADAPT trial presented during American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) Annual Meeting and Myasthenia Gravis Foundation of America (MGFA) Scientific Session.
  - ADAPT Phase 3 trial results of efgartigimod for treatment of gMG published in The Lancet Neurology.
  - Full Phase 2 trial results of efgartigimod for treatment of pemphigus published in British Journal of Dermatology.

- ARGX-117 (C2 blocker):
  - Phase 1 data presented during July R&D day showing favorable safety profile and potential for infrequent dosing schedules.
  - Phase 2 trial in multifocal motor neuropathy (MMN) initiated at end of 2021.

- ARGX-119 (MuSK agonist):
  - Announced next pipeline candidate during July R&D day with pipeline-in-a-product potential in neuromuscular indications.

- Cusatuzumab (anti-CD70):
  - Regained worldwide rights to cusatuzumab from Cilag GmbH International, one of the Janssen Pharmaceutical Companies of Johnson & Johnson (Cilag), and started evaluation process for potential alternatives to advance program through partnership.

Corporate Achievements

650
Employees

argenx expanded to 650 employees (per December 31, 2021) to support growth of business, including fully staffed commercial teams in the U.S. and Japan.

Karl Gubitz

Appointed Karl Gubitz as Chief Financial Officer. Prior to joining argenx, Mr. Gubitz was Vice President of Finance within the Global Oncology business of Pfizer.

Wim Parys

Chief Medical Officer Wim Parys, M.D. announced plans to retire on March 31, 2022 and argenx announced that Luc Truyen, M.D., Ph.D., Vice President of Research & Development Operations is to assume the role of Chief Medical Officer. Prior to joining argenx, Dr. Truyen was the Global Head of Development and External Affairs – Neuroscience at Johnson & Johnson.

Collaborations

- Announced exclusive partnership agreement with Zai Lab Limited (**Zai Lab**) under which we received a total of $175 million in collaboration payments in 2021 to develop and commercialize efgartigimod in Greater China.
- Initiated collaboration and license agreement with Elektrofi, Inc. (**Elektrofi**) to explore new SC formulations for current and future pipeline candidates.
- Announced exclusive partnership agreement with Medison Pharma Ltd. (**Medison**) for the commercialization of efgartigimod in gMG in Israel.

Financial Highlights

$2.3 billion

Cash

Cash position of $2.3 billion (cash, cash-equivalents and current financial assets) enabling execution of our ambitious strategy objectives.

$348.7 million

Operating Income

Operating income $348.7 million.

$408.3 million

Loss

Loss $408.3 million.

$1.15 billion

Raised

Raised $1.15 billion in gross proceeds in global offering of 3,593,750 ordinary shares (including ordinary shares represented by American Depositary Shares (ADSs)), which included the full exercise of the underwriters' option to purchase 468,750 additional ADSs.

2022

Outlook

With the approval of VYVGART™ as the first-and-only approved neonatal Fc receptor (FcRn) blocker in the U.S and Japan, we enter 2022 in a strong position to execute on our plans for a global launch and advance our pipeline of assets, including further efgartigimod development, across our four commercial franchises in neuromuscular, hematology, dermatology and nephrology.

Global Efgartigimod Launch

- EMA decision expected in the second half of 2022.
- argenx Canada was established in first quarter of 2022 in preparation for a potential Health Canada approval request and, if granted, commercial launch in Canada.
- Zai Lab on track to file for approval in Greater China of efgartigimod by mid-2022.
- Additional distribution partnership agreements for other territories expected to be announced in 2022 that would expand global patient reach.

Pipeline of Differentiated Antibody Candidates

- Topline data from four registrational trials of efgartigimod expected across four indications, including gMG, ITP, PF and PV, and CIDP:
  - ADAPT-SC: Topline data of SC efgartigimod for gMG expected in first quarter of 2022.
  - ADHERE: Topline data of SC efgartigimod for CIDP expected in first quarter of 2023.
  - ADVANCE: Topline data of intravenous efgartigimod for primary ITP expected in second quarter of 2022.
  - ADVANCE-SC: Topline data of SC efgartigimod for primary ITP expected in first quarter of 2023.
  - ADDRESS: Timing of topline data of SC efgartigimod for PF and PV is currently under review given the geopolitical events in Ukraine.

- ALKIVIA registrational trial of SC efgartigimod for myositis to start in second quarter of 2022.

- Clinical trials to start in 2022 in four additional indications through partnership agreements with Zai Lab and IQVIA LTD (**IQVIA**):
  - Zai Lab to launch proof-of-concept trials in two kidney indications, lupus nephritis (LN) and membranous nephropathy (**MN**).
  - IQVIA to launch proof-of-concept trials in primary Sjögren's syndrome (**SjS**) in second half of 2022 and COVID-19-mediated postural orthostatic tachycardia syndrome (**POTS**) in mid-2022.

- Phase 2 trial of ARGX-117 for delayed graft function and/or allograft failure after kidney transplantation.

- Phase 1 dose-escalation trial of ARGX-119 to start after Clinical Trial Application filing in fourth quarter of 2022.

ARGX-117

ARGX-119

During our July 2021 R&D Day, we introduced our long-term 'argenx 2025' vision to becoming a global, integrated immunology company including the following goals:

- First, we hope to make efgartigimod globally available to patients across our expanding commercial franchises.

- Second, we aspire to make efgartigimod either commercially available or in clinical development in fifteen active indications.

- Third, we plan to make progress across our broader immunology pipeline with ARGX-117 in multiple late-stage trials and demonstrate proof-of-concept with ARGX-119.

- Fourth and finally, we will invest in the continued expansion of our differentiated pipeline through the IIP and aim to continue to generate one new asset into the pipeline each year.

1

Presentation of the Group

Contents

Our Values

Our values guide our business relationships and collaborations both within and beyond our walls.

We thrive on curiosity and trust in the power of the team to help us identify immunology breakthroughs. We are inspired by patients to translate these breakthroughs into medicines. The resilience and hope of patients gives us purpose, empowering us to work with urgency because we know they are waiting.

Co-Creation
We create through collaboration.

Humillity
We listen to patients and their communities.

Excellence
We live by our reputation for data-driven decision-making.

Empowerment
We build our people based on strengths to benefit the broader team.

Innovation
We live to innovate and do so at every step.

1 Presentation of the group

1.1 Company Profile

1.1.1 General

We are a commercial-stage, global, fully-integrated biotechnology 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 Immunology Innovation Program (**IIP**). We have a particular focus on neuromuscular, hematology, dermatology and nephrology indications through our growing commercial franchises. 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, which will be marketed as VYVGART™ (efgartigimod alfa-fcab), for the treatment of gMG in adult patients who are AChR antibody positive. On January 20, 2022, the Japan 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. With these regulatory milestones, VYVGART™ is the first-and-only approved neonatal FcRn blocker in the U.S and Japan.

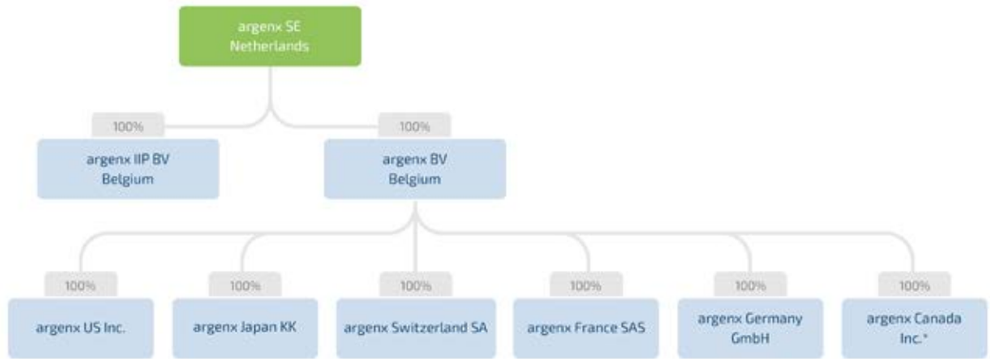
argenx is a Dutch European public company (Societas Europaea) with its statutory seat in Rotterdam, the Netherlands. argenx is registered with the trade register of the Dutch Chamber of Commerce under number 24435214. argenx's registered office is at Willemstraat 5, 4811 AH, Breda, the Netherlands. argenx was incorporated on April 25, 2008 in the Netherlands and under Dutch law. Its commercial name is "argenx" and, since April 26, 2017, its corporate name is "argenx SE". argenx has a one-tier governance structure consisting of an executive director and non-executive directors.

The ordinary shares in argenx are listed on the regulated market of Euronext Brussels in Belgium under ISIN NL0010832176 under the symbol "ARGX". argenx's 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".

argenx is the top entity of the Group and the sole shareholder of

- argenx IIP BV, a private company with limited liability (*besloten vennootschap*) 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*) 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 Delaware, U.S., having its registered office in Wilmington, Delaware and its address at 33 Arch Street, Boston, Massachusetts 02110;
  - argenx Japan K.K., 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 Route de Chêne 30, 1208 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 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; and
  - argenx Canada Inc., incorporated under the laws of Canada, having its registered office in Toronto, Canada and its address at 19 Toulon Crescent, Vaughan, Ontario, Canada, L4H 2X3.

The following chart provides with an overview of the Group as of December 31, 2021 and on the date of this Universal Registration Document. Percentages refer to both the share of capital and voting rights.



(*) argenx Canada Inc. was incorporated on February 14, 2022.

1.1.2 History

We were founded on April 25, 2008 as arGEN-X B.V. as a company with limited liability (*besloten vennootschap*) incorporated under the laws of the Netherlands, having its registered seat in Breda, the Netherlands. On May 28, 2014, the company was converted into a public limited company (*naamloze vennootschap*) with the legal name arGEN-X N.V, in preparation of our initial public offering. Since the successful initial public offering on July 10, 2014, our shares are listed on the regulated market of Euronext Brussels. On April 28, 2016, we changed our legal name to argenx N.V. to align with our logo and tradename. On April 26, 2017, the company was converted into a Dutch European public company (*Societas Europaea* or SE) with the legal name argenx SE, followed by the successful initial public offering of our ADSs on Nasdaq in New York.

On August 28, 2009, our first subsidiary argenx BV was incorporated in Belgium and on August 5, 2020, our subsidiary argenx IIP BV was incorporated also in Belgium.

On December 17, 2021, our first product VYVGART™ for the treatment of gMG in the U.S. was approved by the FDA, moving us forward from a clinical-stage to a commercial-stage biotechnology company. On January 20, 2022, VYVGART™ for the treatment of gMG was approved in Japan.

1.1.3 Overview

Our Pipeline

- *Efgartigimod (FcRn blocker)*: Efgartigimod is a human IgG1 Fc fragment that is designed to target the 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 immunoglobulins that are not recycled by FcRn. IgGs that bind to FcRn are rescued from lysosomal. 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.
  - gMG: In May 2020, we announced positive topline results from the Phase 3 ADAPT trial of intravenous (**IV**), efgartigimod for the treatment of gMG. The topline results from the ADAPT 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 trial and the subsequent open-label extension (ADAPT+) formed the basis for the regulatory approvals of VYVGART™ in the U.S. (December 17, 2021) and Japan (January 20, 2022).

- Registrational trials are ongoing in four additional autoimmune indications with an additional registrational trial to start in the second quarter of 2022:
  - ITP: The ADVANCE trial of IV efgartigimod was initiated in the fourth quarter of 2019 and topline data are expected in the second quarter of 2022. The ADVANCE-SC trial of SC efgartigimod started in the fourth quarter 2020 and topline data are expected in the first quarter of 2023.
  - PV and PF: The ADDRESS trial of SC efgartigimod was initiated in 2020. Timing of topline data is currently under review given the geopolitical events in Ukraine.
  - CIDP: The ADHERE trial of SC efgartigimod was initiated at the end of 2019 and topline data are expected in the first quarter of 2023.
  - BP: The BALLAD trial of SC efgartigimod was initiated at the end of 2021 and an interim analysis is planned of patients.
  - myositis: The ALKIVIA trial of SC efgartigimod will initiate in the second quarter of 2022.
- Clinical trials to start in 2022 in four additional autoimmune indications through partnership agreements with Zai Lab and IQVIA:
  - Zai Lab to launch proof-of-concept trials in two kidney indications, LN and MN.
  - IQVIA to launch proof-of-concept trials in primary SjS in second half of 2022 and COVID-19-mediated POTS in mid-2022.

- *ARGX-117 (C2 inhibitor)*: ARGX-117 is a novel complement inhibitor targeting complement component 2 (**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 four commercial franchises.
  - Phase 1 data of ARGX-117 were reported in July 2021 showing a favorable safety profile across single and multiple ascending doses of both IV and SC formulations. Pharmacokinetic (**PK**) and pharmacodynamic (**PD**) profiles demonstrated potential for infrequent dosing schedules.
  - First Phase 2 proof-of-concept trial started at end of 2021 in MMN with second Phase 2 proof-of-concept trial to start in 2022 in delayed graft function and/or allograft failure after kidney transplantation.
- *ARGX-119 (MusK agonist)*: ARGX-119 is an agonist SIMPLE Antibody™ to the muscle-specific kinase (**MuSK**) receptor with potential in multiple neuromuscular indications. Phase 1 dose-escalation trial to start after Clinical Trial Application filing in fourth quarter of 2022.
- *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.
- *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 acute myeloid leukemia (**AML**) blasts but not on hematopoietic stem cells.
  - In June 2021, we regained global rights to cusatuzumab from Cilag following the termination of a collaboration and licensing agreement to develop cusatuzumab in AML and myelodysplastic syndromes (**MDS**)
  - We continue to evaluate potential alternatives to advance cusatuzumab through partnership
- In addition to our wholly-owned pipeline, we have candidates that emerged from the IIP that have been out-licensed to a partner for further development and for which we have milestone, royalty or profit-share agreements. These candidates include:
  - ARGX-109 (GB224), a SIMPLE Antibody™ inhibitor of IL-6 and out-licensed to Genor BioPharma
  - ARGX-112 (LP-0145), a SIMPLE Antibody™ inhibitor of IL-22R and out-licensed to LEO Pharma
  - ARGX-114 (AGMB-101), a SIMPLE Antibody™ agonist to the MET receptor and out-licensed to AgomAb Therapeutics
  - ARGX-115 (ABBV-151), a SIMPLE Antibody™ inhibitor of GARP-TGF-b1 and out-licensed to AbbVie
  - ARGX-116 (STT-5058), a SIMPLE Antibody™ inhibitor of ApoC3 and out-licensed to Staten Biotechnology

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 have committed to continued investment in the IIP. As at the date of this Universal Registration Document, we have executed on our commitment and aim to continue to bring forth at least one new asset per year from the IIP.

Examples of key collaborations with scientific and academic partners:

- Efgartigimod emerged from a collaboration with Professor Sally Ward and UT Southwestern that later became one of the blueprints for our IIP. Professor Ward's research identified the crucial role that FcRn plays in maintaining and distributing IgGs throughout the body, in 2013. Efgartigimod is a human IgG1 Fc fragment that is equipped with ABDEGTM 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 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.

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.

- **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 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®**, **ABDEGTM**, **POTELLIGENT®**, and ***DHS*** mutations focus on engineering the Fc region of antibodies in order to augment their intrinsic therapeutic properties. In addition, we obtained a non-exclusive research license and option from Chugai 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.
- 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 extended 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.

1.1.4 Recent Developments

On February 21, 2022, Russia announced that it proposed to recognise the so-called Donetsk People's Republic and Lugansk People's Republic as independent republics and on February 24, 2022, Russia further announced the commencement of what it described as a "special military operation" in Ukraine. Since such announcement, Russian forces have entered Ukraine and, as at the date of this Universal Registration Document, there is an ongoing military conflict in Ukraine. In connection with these events, new sanctions have been imposed by the U.S. and European Union, as well as many other countries around the world, on certain Russian companies and Russian individuals, with the nature and extent of these sanctions evolving on an ongoing basis.

This ongoing conflict between Russia and the Ukraine has a direct, limited impact on our operations, given that we are

conducting clinical trials in a large number of jurisdictions, including Russia and Ukraine. Due to the conflict, we are in some cases unable to ship samples from research sites to our third party central laboratory for analysis, recruited patients may no longer be able to participate in our clinical trials, and difficulties with recruiting patients in Russia and Ukraine might have an indirect limited impact on our business actives as we seek alternative recruitment options. Study data collected at Russian or Ukrainian sites may not be fit for submission due to incompleteness or due practical limitations on auditability of the data. At this time we do not expect a material negative impact on our operations as a result of the crisis, but we do expect timing of topline data for the ADDRESS trial of SC efgartigimod for PF and PV may be delayed, although we currently cannot assess if this is the case and how significant such delay could be. We continue to assess the developments on a daily basis.

We do not generate revenues in Russia or the Ukraine and we do not expect the conflict as known to us at the date of this Universal Registration Document to have a material impact on our future sales. Our supply chains have been directly affected in some cases, where we are unable to ship study drug to clinical sites, but as we are not supplying from Russia or the Ukraine but only to these countries for ongoing development activities, we expect the impact will be limited to ongoing clinical studies in these countries. In addition, we expect an overall increase in prices caused by the conflict and global inflation.

Our economic performance is, at the date of this Universal Registration Document, not directly impacted by the conflict. We currently expect the additional costs for any delays and the opening of additional trial sites to be relatively limited and not material to our overall financial performance.

1.2 Strategy and objectives

1.2.1 Company's Strategies

Our goal is to deliver therapies that are either first-in-class or best-in-class to patients suffering from neuromuscular, hematology, dermatology and nephrology indications 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 approval of VYVGART™ as the first-and-only approved neonatal FcRn blocker in the U.S and Japan, we have already taken the first steps in executing our plans for a global launch for VYVGART for the treatment of gMG. We expect EMA decision on approval in the second half of 2022 and aim for further approvals in other jurisdictions in the course of the year. We have already built our commercial infrastructure to support the launch of VYVGART™ in the U.S. and in Japan as well as build out additional commercialization infrastructure to support a rapidly growing number of indications in our key territories, the U.S., Europe and Japan.
- **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, COVID-19 mediated POTS, SjS, MN and LN. By the end of 2024, we aim to be ready for four additional commercial launches of gMG (with SC efgartigimod), ITP, PV and CIDP. We expand the use of our products and product candidates in existing indications by developing new formulations, such as a subcutaneous version of efgartigimod, that may reach more patient groups by capturing different patient preferences and providing additional optionality with regards to dosing.
- **Advance our pipeline of assets.** In addition to new indications for efgartigimod, we plan to advance our other product candidates. In particular, we plan to advance the clinical development of ARGX-117 in multiple Phase 2 proof of concept trials in MMN and delayed graft function in the context of kidney transplant; to advance ARGX-119 and early-stage pipeline candidates in our commercial franchises, the neuromuscular, hematology, dermatology and nephrology franchises; and to 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 expanding 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 trials and demonstrate proof-of-concept with ARGX-119. Finally, we will invest in the continued expansion of our differentiated pipeline through the IIP and aim to continue to generate one new asset into the pipeline each year.
- **Continue to build innovation into every step of our development, highlighted by our collaborative IIP translating immunology breakthroughs into medicines.** The 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 chapter 1 "Presentation of the Group", 2 "Risk Factors" and 3 "Sustainability at argenx" in this Universal Registration Document, 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 and are working on the ongoing launch of the commercialization of VYVGART™.

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, 2021 up to the date of this Universal Registration Document.

For more information, please refer to chapter 2 "Risk Factors", chapter 1 "Presentation of the Group" and to note 29 "Commitments" of our consolidated financial statements in chapter 7 "Consolidated Financial Statements – audited as of and for the years ended December 31, 2021, 2020 and 2019".

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. These companies are highly sophisticated and often strategically collaborate with each other.

We compete with a wide range of pharmaceutical companies, biotechnology companies, academic institutions and other research organizations for novel therapeutic antibody targets, new technologies for optimizing antibodies, talent, financial resources, intellectual property rights and collaboration opportunities. Many of our competitors and potential competitors have substantially greater scientific, research and product development capabilities as well as greater financial, manufacturing, marketing and sales and human resources than we do. In addition, there is intense competition for establishing clinical trial sites and registering patients for clinical trials. Many specialized biotechnology firms have formed collaborations with large, established companies to support the research, development and commercialization of products that may be competitive with ours. Accordingly, our competitors may be more successful than we may be in developing, commercializing and achieving widespread market acceptance.

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 Inc. (Humira/rheumatoid arthritis); Amgen Inc. (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 (Remicade/rheumatoid arthritis and Stelera/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 for the treatment of adult patients with gMG who are AChR antibody positive and that GSK, Roche, Novartis AG, CSL Behring, Grifols, S.A., BioMarin Pharmaceutical Inc., Curavac, UCB S.A./RA Pharma, DAS Therapeutics, Takeda, RemeGen, Immunovant, Cartesian Therapeutics, Horizon Therapeutics, AstraZeneca PLC, Chugai Pharma/Genentech, Regeneron/Alnylam and Johnson & Johnson Innovation Inc., among others, are developing drugs that may have utility for the treatment of MG. Competition for other (potential) future indications is also fierce, with significant development activities in almost all of the indications where we are currently developing or planning to develop our product or product candidates.

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 autoimmune, 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 million. A PRV entitles the holder to FDA priority review of a single new drug application or biologic license application (**BLA**), which reduces the target review time and may potentially lead to an expedited approval. We expect to redeem the PRV for a future marketing application for efgartigimod for another indication.

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 URD.

Autoimmune Pipeline

Program	Indication	Preclinical	Phase 1	Proof of Concept	Registrational	Commercial
VYVGART	gMG					
Efgartigimod	gMG (ADAPT)					
	CIDP (ADHERE)					
	Myositis (ALKIVIA)					
	Pemphigus (ADDRESS)					
	Bullous Pemphigoid (BALLOON)					
	ITP (VIVACE)					
	ITP (VIVACE)					
	Membranous Nephropathy					
	Lupus Nephritis					
	Sjogren's Syndrome					
	COVID-19 Mediated Postural Orthostatic Tachycardia Syndrome					
ARGX-117	Multifocal Motor Neuropathy					
	Delayed Graft Function After Kidney Transplant					
ARGX-119	Neuromuscular Indications					
ARGX-120	Undisclosed					
Non-Autoimmune Programs						
Cusatuzumab	AML					
ARGX-118	Airway Inflammation					

Key: NEUROMUSCULAR HEMATOLOGY DERMATOLOGY NEPHROLOGY

argenx

1.3.1 VYVGART™

Approval

On December 17, 2021, the FDA approved VYVGART™ (efgartigimod alfa-fcab) for the treatment of gMG in adult patients who are AChR antibody positive. 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, Japan's 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. With these regulatory milestones, VYVGART™ is the first-and-only approved neonatal FcRn blocker in the U.S. and Japan.

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 anti-acetylcholine receptor antibody-positive refractory generalised myasthenia gravis (REGAIN): a phase 3, randomised, 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 trial, which were published in the July 2021 issue of The Lancet Neurology.

Input from the gMG community was integrated into the ADAPT trial design. Through listening to and learning from the gMG patient community, we understood that every gMG patient experiences the course of disease differently. As a result, we designed a trial to reflect the individualized nature of gMG with a dosing approach that would be adapted to each patient's individual response.

The Phase 3 ADAPT trial was a randomized, double-blind, placebo-controlled, multi-center, global 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 trial and were treated. Patients were eligible to enroll in ADAPT regardless of antibody status, including patients with AChR antibodies (AChR-Ab+) 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 trial met its primary endpoint, demonstrating that significantly more anti-AChR antibody positive gMG patients were responders on the 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.

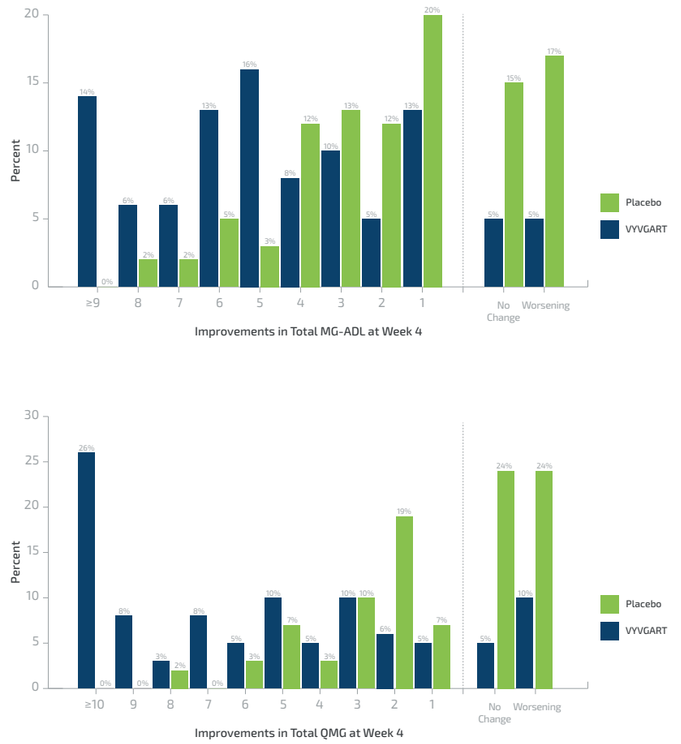


Figure 1: Percentage of patients with MG-ADL and QMG total score change four weeks after initial infusion of the first cycle in AChR-Ab positive population.

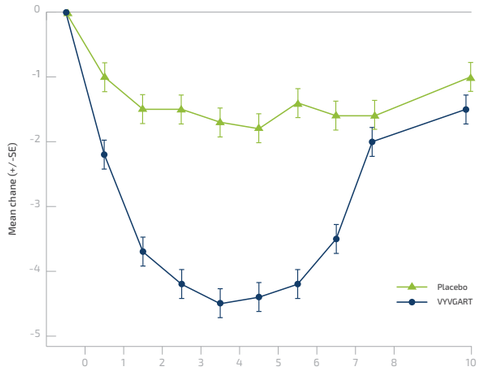


Figure 2: Mean change in total MG-ADL from cycle 1 baseline over time in AChR-Ab positive population.

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 United Kingdom, Hong Kong and Canada for eligible patients.

Commercialization and Regulatory Plans

The U.S. commercial launch for VYVGART™ is ongoing following the December 17, 2021 FDA approval. The Japan commercial launch of VYVGART™ is intended to start after the National Health Insurance (**NHI**) drug price listing, expected approximately 90 days after the approval on January 20, 2022. We have established our own sales force in the U.S. and Japan for VYVGART™ for the treatment of gMG. We plan to expand our own sales and marketing capabilities and promote our products and product candidates if and when regulatory approval has been obtained in the relevant jurisdictions. An MAA for efgartigimod for the treatment of gMG is currently under review with the EMA with an anticipated decision in the second half of 2022. argenx Canada was established in first quarter of 2022 in preparation for a potential Health Canada approval request and if granted commercial launch in Canada.

Development and commercialization may also be done through collaborations with third parties. In January 2021, we entered into an exclusive license agreement with Zai Lab for the development and commercialization of efgartigimod in China, Taiwan, Hong Kong and Macau. We expect Zai Lab to be able to file for approval in Greater China by mid-2022. Under the terms of the strategic agreement with Zai Lab, we received a $75 million upfront payment in the form of 568,182 newly issued Zai Lab shares calculated at a price of $132 per share and a $75 million guaranteed development cost sharing payment and are entitled to a $25 million milestone payment in connection with FDA approval of VYVGART™. We will also be eligible for tiered royalties based on annual net sales of efgartigimod in China, Taiwan, Hong Kong and Macau. In October 2021, we announced an exclusive distribution agreement with Medison to commercialize efgartigimod for gMG in Israel. Medison will also be responsible for seeking requisite regulatory approvals, and we expect Medison to be able to file for approval in Israel in the second quarter of 2022. We intend to sign additional distribution partnerships for other territories.

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 immunoglobulins that are not recycled by FcRn. IgGs that bind to FcRn are rescued from lysosomal. 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. At the date of this URD, Efgartigimod has been evaluated in over 600 subjects and has been observed to significantly reduce concentrations of all IgG subtypes without decreasing levels of other immunoglobulins or human serum albumin, which is also recycled by FcRn.

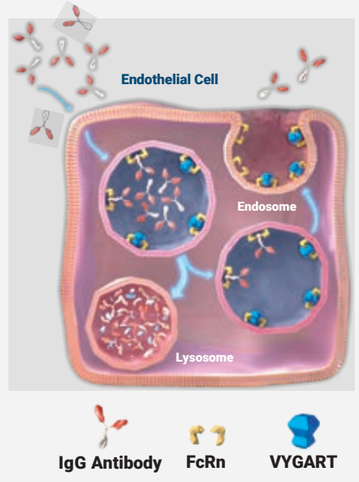


Figure 3: Efgartigimod's mechanism of action blocks the recycling of IgG antibodies and removes them from circulation

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 homeostatis of albumin or immunoglobulins other than IgG and no serious adverse events as defined by the competent authorities related to efgartigimod infusion were observed.

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.

At the date of this URD, we are evaluating efgartigimod in six autoimmune indications where significant unmet need exists despite the availability of commonly used therapies. These include gMG, CIDP and myositis within our neuromuscular franchise; ITP within our hematology franchise; and PV and PF and BP within our dermatology franchise. In 2022, we announced that we will expand into four additional autoimmune indications, including LN and MN within our nephrology franchise and primary SjS and post-COVID-19 mediated POTS.

Indication Selection Strategy

In selecting our indications for efgartigimod, we utilize the following strategy:

- We first start with a strong, unifying biological rational. 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 immunoglobulin (**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 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 neuromuscular, hematology, dermatology, and nephrology 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 and the ENHANZE® (licensed from Halozyme) SC formulation.

IV

We conducted a Phase 1 clinical trial in healthy volunteers to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, 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 multiple ascending doses of efgartigimod or placebo up to a maximum of 25 mg/kg.

In the multiple ascending dose 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 multiple ascending dose 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. Pharmacokinetic 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 multiple ascending dose portions, no significant reductions in IgM, IgA or serum albumin were observed.

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

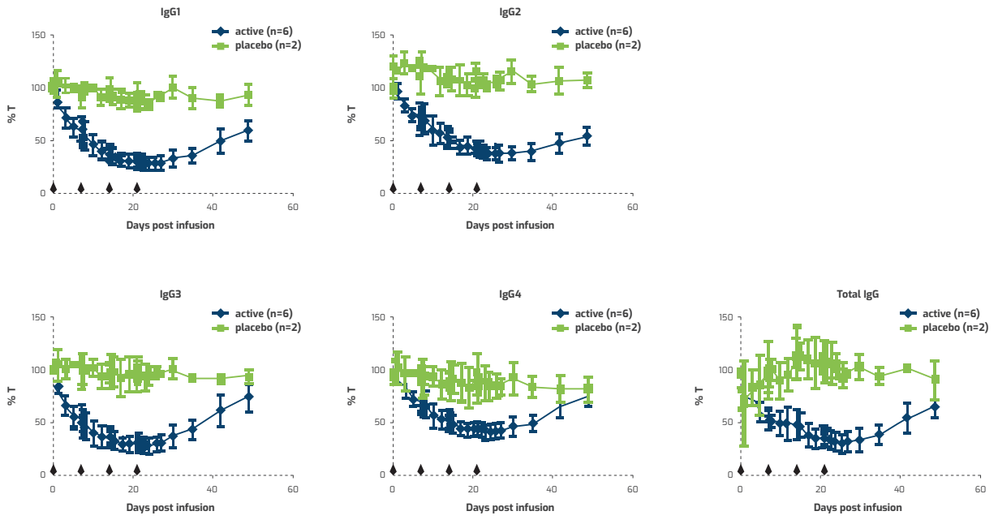


Figure 4: Reduction in the levels of four IgG antibody classes and total IgG levels in the multiple ascending dose part of our Phase 1 clinical trial of efgartigimod in healthy volunteers at a dose of 10 mg/kg every seven days.

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 neonatal Fc receptor FcRn and complement component C2.

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

SC – Partnership with Elektrofi
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. See section 1.5.1 "Our Exclusive License with Elektrofi for efgartigimod" for more information.

1.3.3 Efgartigimod (formerly ARGX-113) Indications

Generalized Myasthenia Gravis (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 myasthenia gravis (**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).

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.

We expect to announce topline results for the ADAPT-SC trial in the first quarter of 2022.

Other trials
In addition, we are currently evaluating efgartigimod in IV formulation, in clinical trials exploring variations on dosing in the gMG, in children with gMG, as well as in a healthy volunteer trial evaluating the immune response after vaccination (PNEUMOVAX 23) while receiving efgartigimod.

Primary Immune Thrombocytopenia (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 immune thrombocytopenia, 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 Syk 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 United States (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 Trials
In the fourth quarter of 2019, the first of two registrational trials, the ADVANCE Phase 3 trial, was initiated to evaluate 10 mg/kg IV efgartigimod for the treatment of primary ITP. The second registrational ADVANCE-SC trial of 1000mg SC efgartigimod for the treatment of primary ITP was initiated in the fourth quarter of 2020. We expect to enroll approximately 156 patients in each trial. Topline data are expected for the ADVANCE trial in the second quarter of 2022 and for the ADVANCE-SC trial in the first quarter of 2023, respectively. The primary endpoint of both trials is the proportion of chronic ITP patients with a sustained platelet count response, defined as achieving platelet counts of at least 50×109/L for at least four of the six visits between weeks 19 and 24 of the trial.

Phase 2 Trial
We completed a randomized, double-blind, placebo-controlled Phase 2 clinical trial to evaluate the safety, efficacy and pharmacokinetics of efgartigimod in 38 adult primary ITP patients, who had platelet counts lower than 30 x 109/L while being on a stable dose of standard-of-care treatments consisting of corticosteroids, permitted immunosuppressants or thrombopoietin receptor agonists, or after having undergone a splenectomy or while being monitored under a 'watch & wait' approach. We conducted the clinical trial at 19 clinical centers across eight countries in the European Union. Patients were randomly assigned to three arms of twelve or 13 patients for the placebo or efgartigimod arms, respectively. All patients in this clinical trial on a drug standard-of-care treatment were to continue to receive their stable dose of standard-of-care treatment as per the protocol. One treatment arm received 5 mg/kg efgartigimod, the second arm received 10 mg/kg efgartigimod and the third arm received placebo. Dosing took place in a three-week period, which included four weekly doses of efgartigimod or placebo. Patient follow-up continued for 21 weeks after treatment. Patients from all three cohorts were eligible to enroll in a one-year open-label extension study at the 10mg/kg dose of efgartigimod, subject to meeting enrollment criteria, including platelet counts lower than 30 x 109/L.

Full results from the Phase 2 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 (**TEAE**) observed characterized as mild (CTCAE Grading 1 and 2). There were no dose-related safety observations and the safety profile was consistent with previous observations in healthy volunteers and myasthenia gravis patients. No increased risk of infection was apparent in the efgartigimod-treated groups compared to the placebo group.

Targeting FcRn with efgartigimod resulted in rapid and selective IgG reduction, and a greater numerical reduction was observed in the efgartigimod 10 mg/kg group, without impacting the levels of other immunoglobulin isotypes. Efgartigimod administration did not result in a reduction of albumin levels, suggesting that the Fc fragment efgartigimod is not interfering with albumin binding or influencing the fate of FcRn.

Reduction in platelet-associated autoantibodies were observed in the majority of patients with clinically meaningful platelet increase.

Efgartigimod-treated groups achieved a higher maximum mean platelet count change from baseline compared to the placebo group. Post hoc analyses requiring greater frequency or duration of platelet count ≥50×109/L, or increased platelet count to ≥100×109/L, demonstrated the efficacy of efgartigimod. Six patients (46%) treated in both efgartigimod groups showed an increase in platelet count >50×109/L on at least two occasions. Additionally, substantially more active-treated patients achieved a platelet count ≥50×109/L for more than 10 cumulative days compared to the placebo group (10 [38%] vs. 0 [0%], respectively).

Adverse event reporting showed no severe bleeding events in any patient, mild bleeding events only were reported in the 10 mg/kg arm and mild and moderate in the 5 mg/kg and placebo arm. Incidence of bleeding events was reduced by efgartigimod treatment as assessed by the World Health Organization bleeding scale, with separation from placebo as early as the third dose in the 10 mg/kg arm. Incidence of bleeding events in the skin was reduced by efgartigimod treatment as assessed by the ITP-BAT bleeding scale, with no clear signal of bleeding events in the mucosa or organs in either treatment arm.

Low titer of anti-drug antibodies was detected in 16.7% of placebo patients and 30.8% of treated patients in the 10 mg/kg arm with no apparent effect on pharmacokinetics or pharmacodynamics.

Phase 3 - IV and SC Trials
In the fourth quarter of 2019, the first potential registrational Phase 3 trial of IV efgartigimod in ITP, the ADVANCE trial, was initiated to evaluate a dose of 10 mg/kg IV efgartigimod. We expect to enroll 156 patients in this Phase 3 trial. The second potential registrational Phase 3 trial of SC efgartigimod in ITP, the ADVANCE SC trial was initiated in the fourth quarter of 2020 to evaluate a dose of 1000 mg SC efgartigimod. We expect to enroll 156 patients in this trial as well. We expect to announce topline results for the ADVANCE and ADVANCE-SC trials in the second quarter of 2022 and first quarter of 2023, respectively.

Pemphigus Vulgaris (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 Pemphigus. Similar to MG and ITP, disease severity of Pemphigus correlates to the amount of pathogenic IgGs targeting desmogleins. Currently, there are an estimated 17,400 pemphigus patients in the United States, 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 (**ABSIS**), 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 Trial
In the fourth quarter of 2020, the registrational ADDRESS 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 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 trial are participating in studies conducted in Ukraine or Russia. Due to the conflict between Russian and Ukraine, we may be unable to fully benefit from the study data collected to date and we may need to recruit additional patients which could delay data read-out points for our studies, although we are currently unable to assess if and by how much such delays would occur. Accordingly, timing of topline data for the ADDRESS trial of SC efgartigimod for PF and PV may be impacted but we are currently unable to assess the full impact due to the rapidly developing situation.

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

In this 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 (DSG) 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 0.26mg/kg/day prednisone within 2-41 weeks.
- a favorable tolerability profile, consistent with data from previous efgartigimod studies.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

Overview of Chronic Inflammatory Demyelinating Polyneuropathy

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 United States.

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. While IVIg therapy can usually control CIDP, most patients require repeated treatments every two to six weeks for many years. This is due to the fact that IVIg monotherapy does not usually lead to long-term remission.

ADHERE Trial

At the end of 2019, we initiated the registrational ADHERE trial evaluating SC efgartigimod for the treatment of CIDP. The ADHERE trial is a randomized, withdrawal study evaluating 1000mg weekly SC efgartigimod expected to enroll approximately 130 patients. The 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 Inflammatory Neuropathy Cause and Treatment (**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 efficacy score in Stage B.

Interim Analysis from ADHERE Trial

In February 2021, we announced a "go" decision to transition into the second, placebo controlled stage of this trial based on a planned efficacy and safety assessment following the enrollment of 30 patients into the initial part of the ADHERE trial. The ADHERE trial is expected to enroll approximately 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 trial in the first quarter of 2023.

Idiopathic Inflammatory Myopathy (Myositis)

Overview of Myositis

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 myopathies were classified as either dermatomyositis (**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 immune-mediated necrotizing myopathy (**IMNM**) and anti-synthetase syndrome (**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 (anti-SRP) and anti-3-hydroxy-3-methylglutaryl-coenzyme A reductase (anti-HMGCR) 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 dermatomyositis in July 2021. Myositis patients are most often treated with high-dose steroids.

ALKIVIA Trial

We intend to initiate the registrational ALKIVIA trial of SC efgartigimod for the treatment of myositis in the second quarter of 2022. We will enroll 180 patients dosed with 1000mg SC efgartigimod in three myositis subtype cohorts, IMNM, ASys and DM. An interim analysis is planned after the first 30 patients of each myositis subtype.

The primary endpoint will be based on the mean total improvement score and additional key secondary endpoints will include time to response, durability of benefits, the quality of life and the individual components of the total improvement score.

Bullous Pemphigoid (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 bullous pemphigoid 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 corticosteroids, 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 BALLAD registrational trial evaluating SC efgartigimod in BO, in the second half of 2021, in which we will enroll 160 patients.

The study population will be newly diagnosed and relapsing patients within one year diagnosis. Patients will be randomized 1-to-1 to receive efgartigimod or placebo for total duration of 36 weeks. Standard of care concomitant medication will consist of prednisone at a starting dose of 0.5 milligram per kilogram per day, and the dose will be adjusted if the

Linda

"It is very important to me and others like me, that new innovations are developed in clinics so that we can continue to have hope for better treatments and an improved quality of life."

patient achieves sustained control of disease activity. The primary endpoint is the proportion of participants in complete remission while on minimal steroids (≤0.1mg/kg/day) for at least eight weeks at week 26. Secondary endpoints relate to cumulative steroid doses, IGA BP score, complete remission off steroids, average itch, control of disease activity, and quality of life measures. An interim analysis of the BALLAD trial is expected after the first 40 patients.

New Efgartigimod Indications
In January 2022, we announced that we will be initiating proof-of-concept trials in four new autoimmune indications through our partnership agreements with Zai Lab and IQVIA:

- Membranous Nephropathy (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.
- Lupus Nephritis (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 Sjögren's Syndrome (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 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.
- COVID-19 mediated postural orthostatic tachycardia syndrome (COVID-19 mediated POTS) has been emerging after resolution of COVID-19 infection in previously healthy patients. 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 POTS to activating autoantibodies to autonomic G-protein coupled receptors (GPCR), 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, which was announced in January 2021, allows us to accelerate development of efgartigimod into new autoimmune indications with Zai Lab taking operational leadership of the Phase 2 proof-of-concept trials.

Zai Lab will initiate Phase 2 proof-of-concept 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 (the **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.

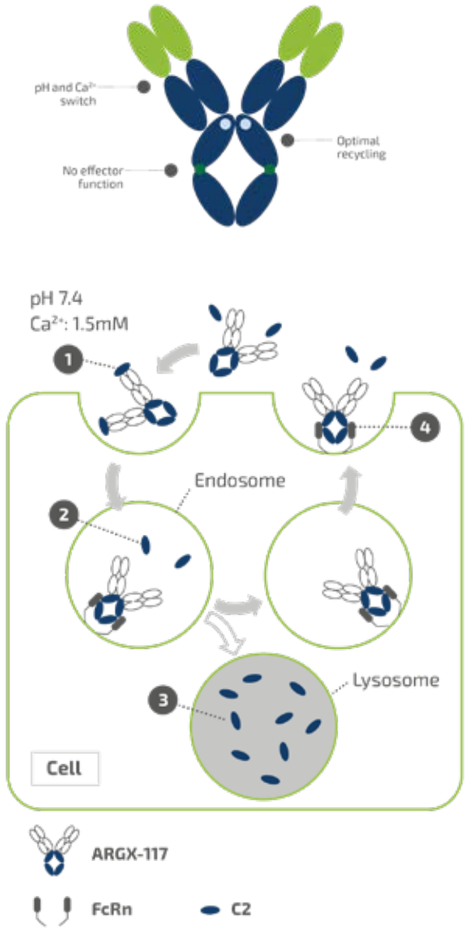
To enable and encourage fast and innovative delivery of the services by IQVIA, the Asset Development Agreement contains an innovative earn-back and bonus plan based upon the performance of IQVIA.

Primary SjS and COVID-mediated POTS are the first indications identified by argenx to be further developed under the Asset Development Agreement.

1.3.4 ARGX-117 Development

ARGX-117 is a highly differentiated therapeutic monoclonal antibody targeting complement component 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

Figure 5



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 Immunology Innovation Program. argenx and Broteio Pharma 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 intravenous formulation, we have exclusive access to Halozyme's ENHANZE® SC drug delivery technology for the C2 target.

Phase 1 Data
We conducted a Phase 1 healthy volunteer trial of IV and SC ARGX-117. This first-in-human clinical study 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 (**SAD**) part, we evaluated 70 subjects and tested up to 80 mg/kg administered IV and up to 60mg/kg administered SC. In the multiple ascending dose (**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 30mg/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 trial in multifocal motor neuropathy in the fourth quarter of 2021 within our neuromuscular franchise.

Overview of Multifocal Motor Neuropathy and Current Treatment
Multifocal Motor Neuropathy (**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 1.5 years 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 immunoglobulin 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.

Delayed graft function and/or allograft failure
A second proof-of-concept trial will be initiated in the second half of 2022 evaluating ARGX-117 for the prevention of delayed graft function (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 delayed graft function (**n**) and allograft failure after kidney transplantation as second 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. As at the date of this Universal Registration Document, we have executed on our commitment and aim to continue to bring forth at least one new asset per year from 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 proprietary 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 pharmacodynamic properties of IgG antibodies. Similarly, our 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.

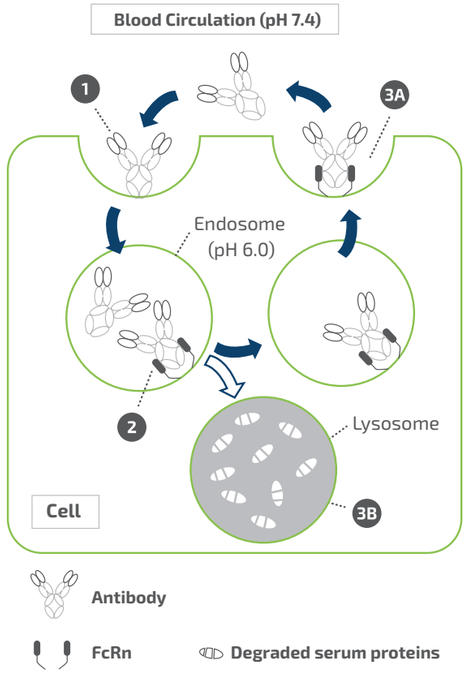


Figure 6: The FcRn-mediated recycling mechanism

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.

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-111, ARGX-109, 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.

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; http://www.tandfonline.com/doi/full/10.1517/14712598.6.11.1161%20).

Chugai and Clayton

In 2020, we entered into a research license and option agreement with Chugai under which we may access

Figure 7

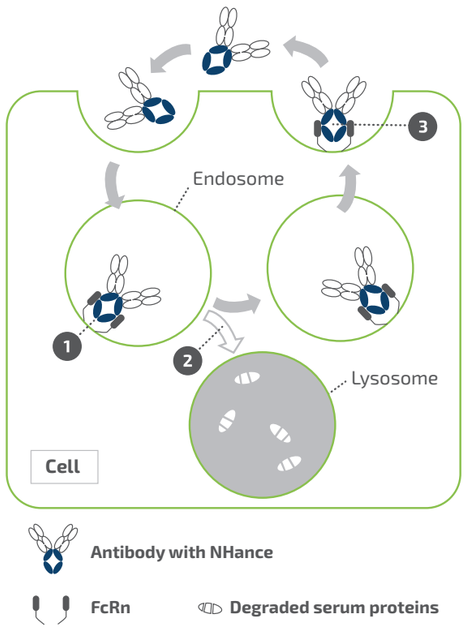
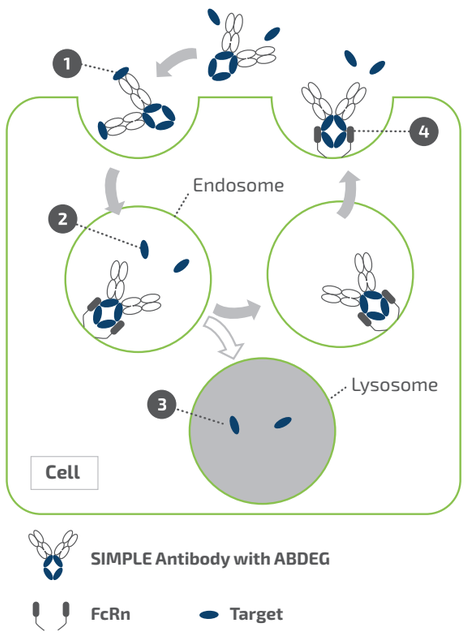


Figure 8: SIMPLE AntibodyTM and ABDEGTM technologies work in concert to sweep diseases targets.



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.

Subcutaneous 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 global collaboration and license agreement with Halozyme was announced in February 2019 and extended 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 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 wholly-owned IIP Programs

Cusatuzumab (formerly ARGX-110)

In June 2021, we announced that we regained worldwide rights to our anti-CD70 antibody cusatuzumab from Cilag.

Following termination of our collaboration, we have elected that Cilag continues to operationally support the treatment and follow-up of patients enrolled in ongoing cusatuzumab clinical trials. Cusatuzumab is being developed for the rare and aggressive hematological cancer AML, as well as high risk MDS. The CULMINATE trial and ELEVATE trial, described below, remain ongoing.

In January 2021, we announced interim data from the Phase 2 CULMINATE trial, evaluating cusatuzumab in combination with azacitidine in newly diagnosed, elderly AML patients who are ineligible for intensive chemotherapy. The 20 mg/kg dose has been selected for ongoing and future trials. Cusatuzumab was observed to be well tolerated and the safety data were consistent with prior studies. Final results from the CULMINATE trial will be presented in a peer reviewed forum.

A set of interim data from the ELEVATE trial, which is evaluating cusatuzumab in combination with venetoclax and azacitidine in newly diagnosed, elderly patients with AML who are ineligible for intensive chemotherapy, has been presented at American Society of Hematology in December 2021. Final results from the ELEVATE trial will be presented in a peer reviewed forum.

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 congenial MG, a rare hereditary subtype of myasthenia gravis, MUSK MG, a rare autoimmune subtype of myasthenia gravis, spinal muscular atrophy (**SMA**) and ALS, both rare, severe neuromuscular indications.

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. ARGX-118 has the following differentiated features:

- it acts on a novel target intended to address mucus plugging, a large unmet need in airway inflammation;
- it has a unique mechanism of action with observed crystal-dissolving properties; and
- its broad potential in severe airway inflammation diseases where mucus plugging plays a key role, including lung attack or asthma exacerbation, allergic bronchopulmonary aspergillosis, and chronic rhinosinusitis with nasal polyps.

ARGX-118 was developed under a collaboration with VIB. Lead optimization work on ARGX-118 for airway inflammation will continue in 2022.

ARGX-120
In addition, we are developing ARGX-120, an antibody against an undisclosed target with application in autoimmune diseases.

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 by planning to retain all development and commercialization rights to those products and product candidates that we believe we can ultimately commercialize successfully, if approved.

We have partnered, and plan to continue to partner, 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, which are 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 S.Á.R.L. (**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 Tregs. Under the terms of the AbbVie Collaboration Agreement, we are responsible for conducting and funding all ARGX-115 (ABBV-151) research and development activities up to completion of IND-enabling studies.

We have 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. Following the exercise of the option, AbbVie will be subject to diligence obligations in respect of continuation of development and commercialization of the licensed product(s), and AbbVie will be solely responsible for all research, development and regulatory costs relating to the products.

In August 2018, AbbVie exercised its option to develop and commercialize ARGX-115 (ABBV-151) 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 $110.0 million, $190.0 million and $325.0 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

In January 2021, we entered into a collaboration agreement with Zai Lab, a commercial-stage biopharmaceutical company, relating to an exclusive out-license for the development and commercialization of efgartigimod in Greater China, including mainland China, Hong Kong, Taiwan and Macau (the **Zai Lab Agreement**). Pursuant to the Zai Lab Agreement, Zai Lab obtains the exclusive right to develop and commercialize efgartigimod in Greater China. Zai Lab will also contribute Chinese patients to our global Phase 3 trials of efgartigimod. Additionally, the Zai Lab Agreement is expected to accelerate efgartigimod global development by initiating multiple Phase 2 proof-of-concept trials in new autoimmune indications under our supervision. In particular, Zai Lab will launch proof-of-concept trials in two new kidney conditions in 2022: LN and MN.

Pursuant to the Zai Lab Agreement, we have received $150.0 million in collaboration payments, comprised of a $75.0 million upfront payment in the form of 568,182 newly issued shares in Zai Lab at a price of $132.00 per share, and a $75.0 million as a guaranteed non-creditable, non-refundable development cost-sharing payment, and we triggered an additional $25.0 million milestone payment following the approval of efgartigimod in the U.S. 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 Greater China.

1.4.3 Our Collaboration with Genor Biopharma for ARGX 109

In October 2012, we entered into an exclusive license agreement with Bird Rock Bio, Inc. (**Bird Rock Bio**, formerly known as RuiYi Inc. and Anaphore, Inc.), to develop and commercialize ARGX-109, which employs our SIMPLE Antibody™ and NHance® technologies and blocks interleukin 6 (IL 6), a cell signaling protein that is an important driver of inflammatory response implicated in the transition from acute to chronic inflammation. In 2018, we and Bird Rock Bio mutually agreed to terminate this exclusive license agreement. Following the termination of our agreement with Bird Rock Bio, we agreed a direct licensing agreement with Genor Biopharma Co. Ltd (**Genor Biopharma**) and Genor Biopharma continues to develop ARGX-109 for the Chinese market.

1.4.4 Our Strategic Partnership with LEO Pharma for LP0145

In May 2015, we entered into a collaboration agreement with LEO Pharma A/S (**LEO Pharma**) to develop and commercialize LP0145 for the treatment of dermatologic indications involving inflammation (the **LEO Pharma Collaboration Agreement**). LP0145 employs our SIMPLE Antibody™ technology and blocks the interleukin-22 receptor (IL-22R) in order to neutralize the signaling of cytokines implicated in autoimmune diseases of the skin. Pursuant to the LEO Pharma Collaboration Agreement, LEO Pharma funded more than half of all product development costs up to 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, CTA approval of a Phase 2a clinical trial for LP0145 was received.

Up through specified periods, LEO Pharma may, against payment of an option fee to us, exercise an option to obtain an exclusive, worldwide license to further develop and commercialize a product, following which 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.

If the option is not exercised, if LEO Pharma does not meet agreed development diligence obligations within a specified time, or if the LEO Pharma Collaboration Agreement is terminated other than for reasons of our breach or insolvency, we have the right to develop and commercialize LP0145 alone, subject to our obligation to pay LEO Pharma low-single digit percentage royalties on net sales of any product covered by any LEO Pharma patents, know-how or rights in research results generated under the collaboration.

Unless earlier terminated, the term of the LEO Pharma Collaboration Agreement ends upon the later of (i) the expiration of the option period, (ii) the expiration of the last license granted under the agreement, and (iii) 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 (CMC) development work in advance of the exercise by LEO Pharma of its option, and updating the provisions regarding the management of patents.

1.4.5 Our Research Collaboration with Staten for STT-5058

In January 2015, we entered into a collaboration agreement with Staten Biotechnology B.V. (**Staten**) to develop and commercialize products in the area of dyslipidemia therapy (the **Staten Collaboration Agreement**). The parties sought to discover and characterize antibodies against a human target with therapeutic relevance in the field of dyslipidemia and / or cardiovascular disease and commence further research programs for targets with therapeutic relevance in these areas. The first research program under the Staten Collaboration Agreement identified STT-5058 for the treatment of dyslipidemia as the initial product candidate. STT-5058 employs our SIMPLE Antibody™ technology and blocks APOC3, a metabolic target involved in triglyceride metabolism. Staten initiated dosing in first-in-human clinical trial of STT-5058. Staten exercised its exclusive option to license STT-5058 in March 2017.

Pursuant to the Staten Collaboration Agreement, the parties were and are jointly responsible for conducting research under a mutually agreed research plan, with Staten reimbursing us for all costs of carrying out our research responsibilities under each research program. Staten is responsible for additional clinical development.

On a research program-by-research program basis, we have granted Staten an option to obtain an exclusive, worldwide, permanent license to research, develop and commercialize products identified in that program within a specified period of time. If Staten exercises this option for a product (as it has for STT-5058), it will be obligated to pay us a percentage of any payments payable to or on behalf of Staten's shareholders in certain events, including the change of control, any licensing, sale, disposition or similar transaction of such product, or otherwise from the research, development or commercialization of that product, in each case, depending on the stage of development and ranging up to the low-twenties, subject to downward proportional adjustment in the event a portion of the proceeds from the applicable transaction does not include payment for such product candidate. Staten is under the diligence obligation to continue to develop and commercialize at least one product during the term of the Staten Collaboration Agreement.

The Staten Collaboration Agreement ended automatically in 2021. In addition, we terminated the research program in connection with the Staten Collaboration Agreement since no targets have been selected within 24 months of the effective date of the relevant research program agreement, other than the target selected for the STT-5058 research program.

1.4.6 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 (the **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.

1.4.7 Our Strategic Partnership with Janssen for cusatuzumab

In December 2018, we entered into a collaboration agreement with Cilag, an affiliate of Janssen Pharmaceuticals, Inc. (**Janssen**), a subsidiary of Johnson & Johnson, to jointly develop and commercialize cusatuzumab (the **Janssen Collaboration Agreement**).

We were notified of Janssen's decision to discontinue the collaboration agreement during a regularly scheduled steering committee meeting on June 4, 2021. Following termination of our collaboration, we have elected that Cilag continue to operationally support the treatment and follow-up of patients enrolled in ongoing cusatuzumab clinical trials. See section 1.3.5 "Immunology Innovation Program".

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 for therapeutic products directed at the human FcRn, including 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 will make 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 Pharmaceutical Co., Ltd. (**Chugai**) allowing us 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 Inc. (**Halozyme**) for the use of certain patents, materials and know-how owned by Halozyme and relating to its ENHANZE® technology (**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 have received an exclusive license from Halozyme is 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 is 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. From the effective date of the ENHANZE® License Agreement, we have a four-year period in which to conduct research and preclinical studies on other target-specific molecules in combination with ENHANZE® and may nominate a maximum of one additional target we have not yet nominated for an exclusive commercial license during the four-year term.

In return for achieving the first patient dosed for efgartigimod -113 Ph3 for ITP we made a $15 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 $10 million to Halozyme per target. We will be obligated to pay clinical development, regulatory and commercial milestones totaling $160 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).

In October 2020, we have 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.

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.

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 chapter 4 "Corporate Governance", our non-executive director James M. Daly is also a non-executive member of the board of directors of Halozyme. Despite this, our entering into 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. 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 chapter 6.11.2 – Related Party Transactions.

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 Therapeutics NV (**AgomAb**) for the use of certain patents 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), an HFG-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 investigational new drug (**IND**) and is subject to further adjustment upon the occurrence of certain financings).

Upon the occurrence of a qualified initial public offer 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 immunology innovation program, to develop an antibody against a novel target in the complement cascade, ARGX-117 (the **Broteio Agreement**). Under the terms of 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 immunology innovation program with VIB to develop antibodies against Galectin-10, the protein of Charcot-Ley-den Crystals, which play a major role in severe asthma and the persistence of mucus plugs, including ARGX-118 (the **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 (**UoT**) for use of certain patents rights relating to the NHance® platform for any use worldwide (the **UoT Agreement**). The UoT 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 UoT 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 UoT Agreement, but in any event does not exceed 1%. In addition, we must make annual license maintenance payments to UoT until termination of the UoT 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 UoT Agreement, we may grant sublicenses to third parties. If we receive any non-royalty income in connection with such sublicenses, we must pay UoT 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 UoT Agreement.

We may unilaterally terminate the UoT Agreement for convenience upon prior written notice. Absent early termination, the UoT Agreement will automatically expire upon the expiration of all issued patents and filed patent applications within the patent rights covered by the UoT 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 for POTELLIGENT®

In October 2010, we entered into a non-exclusive in-license agreement with BioWa, Inc. (**BioWa**) for 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 **POTELLIGENT® License Agreement**). Pursuant to the POTELLIGENT® License Agreement, we are granted a non-exclusive right to use POTELLIGENT® to research, develop and commercialize antibodies and products containing such antibodies using POTELLIGENT®. 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 successfully applied POTELLIGENT® to cusatuzumab, an anti-CD70 mAb, and ARGX-111, an anti-c-Met mAb, under the POTELLIGENT® License Agreement.

Upon commercialization of our products developed using POTELLIGENT®, we will be obligated to pay BioWa 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 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 Agreement, we have the right to grant sublicenses to third parties.

We may terminate the POTELLIGENT® License Agreement at any time by sending BioWa prior written notice. Absent early termination, the POTELLIGENT® License Agreement will automatically expire upon the expiry of our royalty obligations under the POTELLIGENT® License Agreement. In the event the 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 Licenses with BioWa and Lonza for POTELLIGENT® CHOK1SV

To scale up production of our product candidates cusatuzumab and ARGX-111 for clinical trial and commercial supply, we required a license to a GMP cell line in which POTELLIGENT® antibodies could be expressed. This cell line, **POTELLIGENT® CHOK1SV**, was jointly developed by BioWa and Lonza. In December 2013 and August 2014, respectively, we entered into non-exclusive commercial in-license agreements for cusatuzumab and ARGX-111 with BioWa and Lonza Sales AG (Lonza) for the use of certain patents and know-how relating to the POTELLIGENT® CHOK1SV technology, which is a combination of Lonza's GS system and BioWa's POTELLIGENT® platform technology, for use in the field of prevention and treatment of human diseases. Under the terms of each commercial license, we received a non-exclusive right to research, develop and commercialize products containing an antibody generated specifically against a specific target using POTELLIGENT® CHOK1SV, namely the target CD70 in the case of cusatuzumab and c-Met in the case of ARGX-111. Both targets are designated as reserved targets under the POTELLIGENT® License Agreement, which continues to govern our research, development and commercialization of products utilizing POTELLIGENT®. Under the terms of each commercial license, 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® CHOK1SV. This right of first negotiation is not applicable in cases

where we intend to grant a global license to a third party to develop and commercialize a product. BioWa retains a right of first negotiation for the exclusive right to develop and commercialize our anti-c-Met antibody ARGX-111, in certain countries only.

Upon commercialization of our products developed using POTELLIGENT® CHOK1SV, we will be obligated to pay both BioWa and Lonza a percentage of net sales as a royalty. We are required to pay a royalty to BioWa on net sales for any specific licensed product under only one license – either the POTELLIGENT® License Agreement or the agreement in relation to POTELLIGENT® CHOK1SV, but not both. The BioWa royalty is tiered, ranging in the low single digits and 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 BioWa patent(s) that covers the product expires or ends. The Lonza royalty varies based on whether the product is manufactured by Lonza, us or a third party, but in any event is in the low single digits and 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 Lonza patent(s) that covers the product expires or ends. In addition, we must make annual commercial license maintenance payments to BioWa on a per product basis which cease with commencement of payment of the BioWa royalty for the respective product, and annual payments to Lonza in the event that any product is manufactured by a party other than Lonza, us or one of our affiliates or strategic partners named in the agreement.

We have assumed certain development, regulatory and commercial milestone payment obligations to both BioWa and Lonza and must report on our progress toward achieving these milestones on an annual basis. We are required to pay such milestones to BioWa under only one license – either the POTELLIGENT® License Agreement or the agreement in relation to POTELLIGENT® CHOK1SV, but not both. Payments related to the development and commercialization of cusatuzumab and ARGX-111 are foreseen under their respective POTELLIGENT® CHOK1SV agreements. Milestones are to be paid on a product-by-product basis, and we are obligated to make development, regulatory and commercial milestone payments to BioWa in aggregate amounts of up to $36.0 million per product should we achieve global annual sales of $1.0 billion. We are obligated to make development, regulatory and commercial milestone payments to Lonza per product, also depending on such product being manufactured by Lonza, us or one of our affiliates or strategic partners or otherwise.

Under the terms of both cusatuzumab and ARGX-111 commercial licenses, we have the right to grant sublicenses to certain pre-approved third parties, but otherwise must obtain BioWa and Lonza's prior written consent.

We may terminate any of the non-exclusive commercial license agreements at any time by sending BioWa and/or Lonza prior written notice. Absent early termination, the agreements will automatically expire upon the expiry of our royalty obligations under the respective agreement. In the event an agreement is terminated for any reason, the license granted to us would terminate but BioWa and Lonza would grant our respective sublicensees a direct license following such termination. In the event an agreement is terminated other than for our failure to make milestone or royalty payments, we would retain the right to sell the respective products then on hand for a certain period of time post-termination. Our royalty payment obligations expire, on a product-by-product and country-by-country basis, on the date that is the later of (i) ten years after the first commercial sale of such product sold in that country under the agreement or (ii) such time as there are no valid claims covering such product.

1.5.11 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 Agreement**) 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 efgartigimod, cusatuzumab ARGX-117, ARGX-119 and LP0145.

Pursuant to the Multi-Product Agreement, 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 only in respect of the first product manufactured using the System. We are obligated to make development, regulatory and commercial milestone payments to Lonza in aggregate amounts of up to £575,000 for the first product manufactured by Lonza, us or one of our affiliates or strategic partners. Through December 31, 2021, we have paid Lonza an aggregate amount of £0.4 million, which includes milestone payments made under the Multi-Product Agreement. Upon commercialization of our products developed using the System, we will be obligated to pay Lonza a percentage of net sales as a royalty for each product manufactured. 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.

We may terminate the Multi-Product Agreement on a product-by-product basis by giving Lonza prior written notice. Lonza may terminate the Multi-Product Agreement solely in case of breach or insolvency events. Absent early termination, the Multi-Product Agreement 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.

1.5.12 Our Collaboration with UCL and Sopartec for GARP

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

In January 2015, we exercised the option we had been 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 (the **GARP License**). Upon the expiration of the GARP Agreement, the GARP License would 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. 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.

1.5.13 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 immunology innovation program to develop antibodies targeting the MuSK, for the treatment neuromuscular diseases, which play a major role at the neuromuscular junction (the **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

1.6.1 Our Exclusive Distribution Agreement with Medison for efgartigimod

In October 2021, we announced an exclusive distribution agreement with Medison to commercialize efgartigimod for gMG in Israel; under the agreement, Medison will also be responsible for seeking requisite regulatory approvals.

1.6.2 Our Exclusive Distribution Agreement with Genpharm for efgartigimod

On January 18, 2022, we entered into a partnership agreement with Genpharm Services FZ-LLC (**Genpharm**), under which Genpharm shall purchase VYVGART™ from us for the resale in the Gulf Cooperation Council (**GCC**) on an exclusive basis for Genpharm's own account and own name (the **Genpharm Agreement**).

1.7 Manufacturing and Supply

We utilize third-party contract manufacturers who act in accordance with the FDA's good laboratory practices (**GLP**) and current good manufacturing practices (**cGMP**) for the manufacture of drug substance and drug product. At the date of this URD, we contract with Lonza based in Slough, United Kingdom, Portsmouth, U.S. and Singapore for all activities relating to the development of our cell banks, development of our manufacturing processes and the manufacturing of all drug substance, thereby using validated and scalable systems broadly accepted in our industry. We use additional contract manufacturers to fill, label, package, store and distribute investigational drug products.

Efgartigimod, cusatuzumab, ARGX-111, ARGX-117, ARGX-119 and LP0145 are each manufactured using the System, which includes an industry-standard mammalian cell culture of a Chinese hamster ovary cell line that expresses the product, followed by multiple purification and filtration steps typically used in producing monoclonal antibodies. See also section 1.5.11 "Our non-exclusive license with Lonza for Multi-product GS Xceed-License".

All of our antibodies are manufactured by starting with cells, which are stored in a cell bank. We have one master cell bank for each product manufactured in accordance with cGMP. Half of each master cell bank is stored at a separate site to ensure that, in case of a catastrophic event at one site, sufficient vials of the master cell bank would remain at the alternative storage site to continue manufacturing.

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 chapter 1.8.2 –Platform Technologies, and our product candidates, as described in chapter 1.8.3 – Product Candidates: Our Wholly-Owned Programs and chapter 1.8.4 – Product Candidates: 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, 2022, our patent portfolio (which includes both proprietary and in-licensed patent families) comprises approximately 300 granted patents and approximately 308 pending patent applications, including approximately 35 issued U.S. patents, approximately 15 granted European patents and approximately 250 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® platforms and the POTELLIGENT® platform.

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 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 United Kingdom, Israel, India and Japan, and pending applications in China and Japan (divisional). In addition, we have a second patent family containing patents granted in the United States (two), Australia, Europe, the United Kingdom, 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, the University of Texas, a patent family containing a granted U.S. patent with composition of matter claims directed to an isolated FcRn-antagonist comprising a variant immunoglobulin 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, China, Eurasia, Europe, Japan, Macao, Mexico, New Zealand and Singapore, and we have 13 patent applications pending in 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 United States 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 immunoglobulin 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 University of Texas 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.

With regard to the POTELLIGENT® platform, which is currently used in the production of our cusatuzumab product candidate, we have non-exclusively licensed from BioWa certain intellectual property rights that relate to different aspects of the POTELLIGENT® platform.

1.8.3 Product Candidates: Our Wholly-Owned Programs

Efgartigimod
With regard to efgartigimod, efgartigimod incorporates the ABDEG™ 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, China, Europe, Hong Kong, Mexico and U.S. (two issued patents in U.S.), which have a basic expiry date in 2034. The other two patent families have basic expiry dates in 2039 and 2040.

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 Leiden University Medical Center (**LUMC**), a Dutch University Hospital based in Leiden, 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 vzw (VIB), an inflammation research center in Ghent, Brussels, and Universiteit Gent, 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.

Our Cusatuzumab Product Candidate
With regard to the cusatuzumab product candidate, we have four issued U.S. patents, and one allowed U.S. patent application, 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. allowed patent application 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, China, Europe, Indonesia, Israel, India, Japan and Russia and patent applications pending in Brazil and Canada. Cusatuzumab incorporates or employs the SIMPLE Antibody™ and POTELLIGENT® platform technologies.

1.8.4 Product Candidates: Our Partnered Programs

Our ARGX-115 (ABBV-151) Product Candidate
With regard to the ARGX-115 (ABBV-151) product candidate, we co-own with, and exclusively license from, the Ludwig Institute for Cancer Research and Université Catholique de Louvain, 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, the Université Catholique de Louvain 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-109 Product Candidate
With regard to the 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, China, Colombia, Hong Kong, Israel, Japan, Mexico, New Zealand, Russia, U.S. and South Africa, and pending patent applications in Brazil, India and 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-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 patent term extension under the Hatch-Waxman Act as compensation for the loss of patent term during the FDA regulatory review process. The period of extension may be up to five years beyond the expiration of the patent but cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent among those eligible for an extension may be extended. 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.

How has life changed because of myasthenia gravis?

Everything changed. I used to be able to do everyday things, like cooking, cleaning and going shopping. I was able to paint and draw, as I had done all my life. Even after I was on disability, I was still able to do most things with a little help. However, by the time I was diagnosed with MG, I could barely breathe and hardly stand. I couldn't hold a paintbrush or a sketchbook. It felt like so much had been taken away from me.

Shortly after I was diagnosed, I bought a house in Oregon with accessibility modifications that would allow me to still be able to do some things on my own. It has a kitchen with low counters so I can do things while in my chair, a stair lift to get me between floors and accessible bathrooms with a roll-in shower.

By the time I was diagnosed with MG, I could barely breathe and hardly stand.

How did you adapt to all these changes going on in your life?

Mentally, I had to accept that everything had changed. I redefined my entire sense of self. How we see ourselves is connected to what we do, and when I went on disability and received my MG diagnosis, I had to stop defining myself as a user interface designer. I've struggled with health problems for most of my life, but MG was the one that really made me reframe my life.

But I didn't slip into a "woe is me" mentality after my MG diagnosis. I try not to let my limitations from my MG frustrate me. Also, I see a therapist and I'm active in several online communities for myasthenia gravis. Having people that I can talk to who know what it's like to have MG has been a comfort, and I've learned so much from them.

Where do you turn for support during a bad day?

I've found a lot of support from online communities. The people in my groups don't live close by, but they are there to give me mental and emotional support when I need it. My sister lives in Tennessee, but she's always there to talk when I want.

Zach

Zach Leans on his Support System to Help Manage his Myasthenia Gravis*

Three years passed between the beginning of Zach's symptoms and his myasthenia gravis (MG) diagnosis. Already dealing with multiple health problems related to a primary immune deficiency, he was frustrated when these new, undiagnosed symptoms muddied the waters and made it more difficult to get the care he needed.

Patient Story

**Paid contributor to MG United.*

1.9 Regulation

Government authorities in the U.S., at the federal, state and local level, and in the European Union 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., our product candidates and products are regulated as biological products, or biologics, under the Public Health Service Act (**PHSA**), and the Federal Food, Drug, and Cosmetic Act (**FDCA**) and their implementing regulations. The failure to comply with the applicable U.S. requirements at any time during the product development process, including nonclinical 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:

- nonclinical laboratory tests, animal studies and formulation studies all performed in accordance with applicable regulations, including the GLP regulations;
- 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 (**GCP**);
- 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;
- review of the product by an FDA advisory committee, if applicable;
- 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 study 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.

Nonclinical Studies and Investigational New Drug Application
Before testing any biological product candidate in humans, the product candidate must undergo nonclinical testing. Nonclinical 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 nonclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the nonclinical 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. 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 trial to commence or on the terms originally specified by the sponsor in the IND. If the FDA raises concerns or questions either during this initial 30-day period, or at any time during the IND process, it may choose to impose a partial or complete clinical hold. This order issued by the FDA would delay either a proposed clinical study 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 GCP requirements. 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 GCP, 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 GCP rules 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. Information about certain clinical studies must be submitted within specific timeframes to the National Institutes of Health for public dissemination at www.clinicaltrials.gov.

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 pharmacodynamics 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 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 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 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 full 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. Any product manufactured by or imported from a facility that has not registered, whether foreign or domestic, is deemed misbranded under the FDCA. Establishments may be subject to periodic unannounced inspections by government authorities to ensure compliance with cGMPs and other laws. Manufacturers may have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting, or refusing inspection by the FDA may lead to a product being deemed to be adulterated.

Review and Approval of a BLA

The results of product candidate development, nonclinical 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 accept for filing 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 the BLA. Once the submission has been accepted for filing, the FDA begins an in-depth review of the application. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act (**PDUFA**) the FDA has ten months in which to complete its initial review of a standard application and respond to the applicant, and six months for a priority review of an application. The FDA does not always meet its PDUFA goal dates for standard and priority reviews. The review process may be significantly extended by FDA requests for additional information or clarification. The review process and the PDUFA goal date may also be extended by three months if the FDA requests or if the applicant otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities and any FDA audits of clinical trial sites to assure compliance with GCPs, the FDA may 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 may issue a complete response letter, which will contain the conditions that must be met in order to secure final 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 or 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 time period goal for reviewing a fast track application 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 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, additional post-approval confirmatory 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. 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.

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 cGMP regulations, 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 cGMP regulations 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 label. 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.

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. A product becomes an orphan when it receives orphan drug designation from the Office of Orphan Products Development (**OOPD**) at the FDA based on an acceptable confidential request made under the regulatory provisions. After 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. 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.

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.

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, including the non-patent and orphan 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 or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

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 nonclinical 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 Drug Price Competition and Patent Term Restoration Act of 1984 (the **Hatch-Waxman Amendments**). The Hatch-Waxman Amendments permit 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 European Union and the United Kingdom

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, the process governing approval of medicinal products in the European Union and the United Kingdom generally follows the same lines as in the U.S. It entails satisfactory completion of pharmaceutical development, non-clinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the medicinal product for each proposed indication. It also requires the submission to relevant competent authorities for clinical trials authorization and to the EMA or to competent authorities in European Union member states for a MAA and granting of a marketing authorization by these authorities before the product can be marketed and sold in the European Union. Following the United Kingdom's departure from the European Union, a separate marketing authorization will be required in order to place medicinal products on the market in the United Kingdom (under the Northern Ireland Protocol, the European Union regulatory framework will continue to apply in Northern Ireland and centralized European Union authorizations will continue to be recognized).

Clinical Trial Approval

In April 2014, the European Union adopted the new Clinical Trials Regulation (EU) No 536/2014, which replaced the Clinical Trials Directive 2001/20/EC effective as of January 31, 2022. The transitory provisions of the new Regulation offer 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 is submitted in the year after the new Regulation became applicable. If the sponsor chooses 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. 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 European Union member states, aims at simplifying and streamlining the approval of clinical trials in the European Union. 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 European Union 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 clinical trial applications.

The United Kingdom has implemented Directive 2001/20/EC into national law through the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended).The extent to which the regulation of clinical trials in the United Kingdom will mirror the new European Union Clinical Trials Regulation that has come into effect is not yet known, however the Medicines and Healthcare products Regulatory Agency (**MHRA**), the United Kingdom medicines regulator, has opened a consultation on a set of proposals designed to improve and strengthen the United Kingdom clinical trials legislation. Such consultation is open until March 14, 2022.

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 European 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 European Union when the application is made, or (ii) without incentives it is unlikely that the marketing of the product in the European Union 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 European Union 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 nor the European Commission or the European Union 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 European Union) and the application for orphan designation will be reviewed by the MHRA, at the time of an MAA for a United Kingdom or Great Britain marketing authorization. The criteria are the same as in the European Union, 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 European Union, 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 European Union regulatory system, an applicant must submit an MAA, either to the EMA using the centralized procedure or to competent authorities in the European Union 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 European Union. Regulation (EC) No. 1901/2006 provides that prior to obtaining a marketing authorization in the European Union, 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 European 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 European Union.

Under the centralized procedure, the Committee for Medicinal Products for Human Use (**CHMP**), established at the EMA is responsible for conducting the assessment of a product to define its risk/benefit profile. The CHMP recommendation is then sent to the European Commission, which adopts a decision binding in all EEA Member States. Under the centralized procedure, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions asked by the CHMP. 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. Since the United Kingdom has left the European Union, Great Britain will no longer be covered by centralized marketing authorizations (under the Northern Ireland Protocol, centralized European Union authorizations will continue to be recognized in Northern Ireland). All medicinal products with a current centralized authorization were automatically converted to United Kingdom marketing authorizations on 1 January 2021. For a period of two years from 1 January 2021, the MHRA may rely on a decision taken by the European 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 will, however, still be required.

European Data and Market Exclusivity
In the European Union, 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 European Union, for a period of eight years from the date on which the reference product was first authorized in the European Union. 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 European Union 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.

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 European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization that is not followed by the placement of the drug on the European Union 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.

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 European Union'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 European Union, 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 European Union under Directive 2001/83/EC, as amended.

The aforementioned European Union rules are generally applicable in the EEA.

Brexit and the Regulatory Framework in the United Kingdom
In June 2016, the electorate in the United Kingdom voted in favor of leaving the European Union (commonly referred to as "Brexit"), and the United Kingdom officially withdrew from the European Union on January 31, 2020. Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the European Union, the United Kingdom was subject to a transition period until December 31, 2020, during which European Union rules continued to apply. However, the European Union and the United Kingdom have 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 United Kingdom and European Union pharmaceutical regulations. At present, Great Britain has implemented European Union legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended). The regulatory regime in Great Britain therefore largely aligns with current European Union regulations, however it is possible that these regimes will diverge in future now that Great Britain's regulatory system is independent from the European Union and the TCA does not provide for mutual recognition of United Kingdom and European Union pharmaceutical legislation. For example, the new Clinical Trials Regulation which became effective in the European Union on January 31, 2022 has not been implemented into United Kingdom law, and a separate application will need to be submitted for clinical trial authorization in the United Kingdom.

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 Minister of Health, Labour and Welfare (the **Minister**), primarily under the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals and Medical Devices (**Pharmaceutical and Medical Device Act**). This entails the satisfactory completion of pharmaceutical development, nonclinical 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 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 PMDA, a person is required to obtain from the Minister 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 Minister a manufacturing license for each manufacturing site.

Marketing Approval
Under the PMDA, it is generally required to obtain marketing approval from the Minister 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 PMDA, 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 Minister, such as GLP and GCP stipulated by the ministerial ordinances of the Minister.

Regulatory Requirements after Marketing Approval
A marketing license-holder that has obtained marketing approval for a new medical product must have that medical product re-examined by the Minister or by the PMDA for a specified period after receiving marketing approval. The purpose of this re-examination process is to ensure the safety and efficacy of a newly approved medical product 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 Minister 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 Minister pursuant to the PMDA.

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 NHI price list published by the Minister. 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 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 European Union, 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 health care 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. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. 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 China, the newly created National Healthcare Security Administration (**NHSA**) an agency responsible for administering China'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 (**NRDL**) 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 China'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 China, 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 NRDL 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 China 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.

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. 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. 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 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 be losing 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.

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 United States. 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 (ASP) 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.

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. 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. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial that compares the effectiveness of any product candidates we may develop to other available therapies to support cost-effectiveness. The conduct of such a clinical trial could be expensive, involve additional risk and result in delays in our commercialization efforts.

In the European Union, 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 European Union 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. European Union 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 European Union 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 European Union. The downward pressure on health care 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 European Union 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 European Union 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 European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, 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 European Union member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union 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 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**) which 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 federal Anti-Kickback Statute. Under the final rules, OIG added safe harbor protections under the Anti-Kickback Statute 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 U.S. federal Anti-Kickback Statute 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 U.S. federal Anti-Kickback Statute, 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 the Centers for Medicare & Medicaid Services (**CMS**) within the U.S. Department of Health and Human Services, 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) 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. Effective January 1, 2022, these reporting obligations were extended to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;
- 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
- European and other foreign law equivalents of each of the laws, 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 health care 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 European Union 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 will be required to spend substantial time and money to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations. Recent healthcare reform legislation has strengthened these federal and state healthcare laws. 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 federal anti-kickback statute 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 are currently under review by the current U.S. presidential administration and may be amended or repealed. 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 Average Manufacturer Price 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. It is unclear how the outcome of this litigation will affect the rule. We cannot predict how the implementation of and any further changes to this rule will affect our business. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the current U.S. presidential administration may reverse or otherwise change these measures, both the current U.S. presidential administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

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.

1.9.6 Healthcare Reform

In the U.S., the European Union and other foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. 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.

Among the provisions of the ACA of importance to our potential product candidates are the following:

- an annual, nondeductible fee on any entity that manufacturers or imports specified branded prescription drugs and biologic products, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices and extending rebate liability to prescriptions for individuals enrolled in Medicare Advantage plans;

- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted or injected;
- expanding the types of entities eligible for the 340B drug discount program;
- establishing the Medicare Part D coverage gap discount program, which requires manufacturers to provide a 50% (increased to 70% effective January 1, 2019 pursuant to subsequent legislation) point-of-sale-discount off the negotiated price of applicable products to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient products to be covered under Medicare Part D;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of the Center for Medicare and Medicaid Innovation (**CMMI**) within CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription product spending.

Since its enactment, some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial, congressional, and executive challenges. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA.

Since its enactment, there have been judicial, Congressional and executive challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact our business.

Prior to the Biden administration, on October 13, 2017, former President Trump signed an executive order terminating the cost-sharing subsidies, or CSRs, that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. On August 14, 2020, the Court of Appeals for the Federal Circuit affirmed a lower court ruling that the federal government is liable to insurers selling marketplace health plans for the loss of cost-sharing reduction reimbursements mandated under the ACA. It is unclear what impact this will have on our business. Further, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. On April 27, 2020, the U.S. Supreme Court reversed the Federal Circuit decision and remanded the case to the U.S. Court of Federal Claims, concluding the government has an obligation to pay these risk corridor payments under the relevant formula. It is unclear what effect this will have on our business.

In addition, CMS published a final rule that would give states greater flexibility as of 2020 in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

On December 20, 2019, former President Trump signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repeals the Cadillac tax, the health insurance provider tax, and the medical device excise tax. It is impossible to determine whether similar taxes could be instated in the future.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These new laws may result in additional reductions in Medicare and other healthcare funding. For example, on August 2, 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per financial year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including without limitation the Bipartisan Budget Act of 2015, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. Following the suspension, a 1% payment reduction will occur beginning April 1, 2022 through June 30, 2022, and the 2% payment reduction will resume on July 1, 2022. Proposed legislation, if passed, would extend this suspension until the end of the pandemic. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

On May 23, 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. However, it is unclear whether the Biden administration will challenge, reverse, revoke or otherwise modify these executive and administrative actions after January 20, 2021.

Recently there has been other types of heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs.

At a federal level, President Biden signed an Executive Order on July 9, 2021 affirming the administration's policy to (i) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs HHS to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's implementing regulations. FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. On September 25, 2020, CMS stated drugs imported by states under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. If implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation (MFN) Model under which Medicare Part B reimbursement rates would have been calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. However, on December 29, 2021 CMS rescinded the MFN rule. Additionally, on November 30, 2020, 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, 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 pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

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 European Union, 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 European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, 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 European Union member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union 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.

1.9.7 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

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Risk Factors

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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 maintain profitability.

We are a commercial-stage biopharmaceutical company with a limited operating history and we have only very recently commenced our transition from clinical-stage to a commercial-stage company. Only VYVGART™ (efgartigimod alfa fcab) for the treatment of gMG has obtained regulatory approval in the U.S. on December 17, 2021 and in Japan on January 20, 2022 and we do not currently have any approvals in any other jurisdictions or for any other product candidates. Since our inception, we have incurred significant operating losses, totaling USD 1,400.2 million of cumulative losses. Our losses resulted principally from costs incurred in research and development, preclinical testing, clinical development of our product and our product candidates as well as costs incurred for research programs, pre-commercial activities and from general and administrative costs associated with our operations. In addition, we expect to continue to incur significant costs associated with our listings in the U.S. and in Europe. In the future, we intend to continue to conduct research and development, preclinical testing, clinical trials and regulatory compliance activities as well as the commercialization of VYVGART™ for the treatment of gMG in the U.S. and in Japan and we intend to continue our efforts to establish and maintain a sales, marketing and distribution infrastructure. These expenses, together with anticipated general and administrative expenses, will result in incurring further significant losses for at least the next several years. We anticipate that our expenses will increase substantially if and as we execute our strategic objectives and as we experience delays or encounter issues relating thereto, including failed studies, ambiguous trial results, safety issues or other regulatory challenges. If our losses become greater than expected, we may require additional financing than anticipated and such financing may not be available to us on acceptable terms or at all.

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

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

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

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

In preparation of our commercial launch of VYVGART™, our cash burn increased significantly in 2021 as compared to 2020 and previous financial years. As disclosed in our consolidated financial statements for the financial year ended December 31, 2021, net cash outflow from our operating activities increased by $208.3 million to a net outflow of $606.8 million for the year ended December 31, 2021, compared to a net outflow of $398.5 million for the year ended December 31, 2020. As disclosed in our previous consolidated financial statements, our cash flows from our operating activities amounted to a net inflow from of $151.3 million (€134.6 million) for the year ended December 31, 2019, a net outflow of $63.5 million (€53.8 million) for the year ended December 31, 2018 and a net outflow of $41.1 million (€36.5 million) for the year ended December 31, 2017. Based on our current plans to expand our commercial infrastructure and differentiated pipeline of assets, we expect our cash burn to continue to significantly increase in 2022. The increased spend will support our transition to an integrated immunology company and is, in particular, expected to be used to build our commercial infrastructure to support the commercialization of VYVGART™ in the U.S. and in Japan for the treatment of gMG and, if approved, for a rapidly growing number of indications in the U.S. and Japan and our other key territories (in the EU), to advance the development of efgartigimod to market regulatory approval for the treatment of ITP, PV, CIDP, BP, myositis, COVID-19 mediated POTS, SjS, MN and LN, to advance clinical development of ARGX-117 in multiple Phase 2 proof of concept trials in MMN and DGF in the context of kidney transplant, to advance ARGX-119 and early stage pipeline candidates in our commercial franchises, the neuromuscular, hematology, dermatology and nephrology franchises, to build out a commercial supply chain to support our global launches of any approved products, to expand our pipeline of future product candidates through the IIP, and to fund other current and future research and development activities and technology development and for working capital and other general corporate purposes.

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

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

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

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

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

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

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

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

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

Clinical trials must be conducted in accordance with the EMA, FDA, PMDA and other applicable regulatory authorities' legal requirements and regulations and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted or ethics committees. In addition, clinical trials must be conducted with supplies of our products and product candidates produced under cGMP requirements and other regulations. Furthermore, we rely on contract research organizations (**CROs**) and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with GCP requirements. To the extent our collaborators or the CROs or investigators fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business. In addition, clinical trials that are conducted in countries outside the European Union and the U.S. may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-European Union and non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the EMA, FDA, PMDA or other regulatory authorities, and apply different standards of diagnosis, screening and medical care.

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

product candidates. Thus, we cannot be sure that we will be able to submit INDs or CTAs or comparable applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or CTAs or comparable applications will result in the EMA, FDA, PMDA or other regulatory authorities allowing clinical trials to begin.

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

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

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

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

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

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

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

Operational impacts of COVID-19

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

We and/or our respective partners evaluate the advancement of each clinical program on a continuous basis taking into account the trajectory of COVID-19. If we and/or one of our partners elect not to move forward with some or all of these clinical programs as a result of the COVID-19 pandemic or otherwise, we would not be entitled to some or all of the future payments which we are eligible to receive under the collaboration agreement with such partner.

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

Since March 2020 when foreign and domestic inspections by the FDA of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. Since April 2021, the FDA has conducted limited inspections and employed remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. The FDA is continuing to complete mission-critical work, prioritize other higher-tiered inspectional needs (e.g., for-cause inspections), and carry out surveillance inspections using risk-based approaches for evaluating public health. As of the date of this Universal Registration Document, ongoing travel restrictions and other uncertainties continue to impact oversight operations. Should the FDA determine that an inspection is necessary for approval of a marketing application and

an inspection cannot be completed during the review cycle due to restrictions on travel, the FDA has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. A complete response letter indicates that the review cycle of the application is complete and the application will not be approved in its present form, and usually describes all of the specific deficiencies in the new drug application identified by the FDA. The applicant may either resubmit the new drug application, addressing all of the deficiencies identified in the letter, withdraw the application, or request a hearing. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. Such restrictions and delays could adversely affect our ability to obtain regulatory approval for and to commercialize our products and product candidates and have a material adverse effect on our business and financial results.

Economic impacts of COVID-19

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

Impacts of COVID-19 on employees or other stakeholders

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

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

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

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

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

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

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

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

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

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

label or even revoke the license, which could harm our reputation and have a material adverse effect on our ability to commercialize VYVGART™.

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

The market for pharmaceutical products is highly competitive. Our competitors we face in the autoimmune field, the field of leukemia and lymphoma and the monoclonal antibody drug discovery field include many established pharmaceutical companies, biotechnology companies, universities and other research or commercial institutions, many of which have substantially greater financial, research and development resources than we have. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products. Smaller and early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, the development of our products. The fields in which we operate are characterized by rapid technological change and innovation. There can be no assurance that our competitors are not currently developing, or will not in the future develop, technologies and products that are equally or more effective or are more economically attractive than any of our current or future technology or product. Competing products or technology platforms may gain faster or greater market acceptance than our products or technology platforms and medical advances or rapid technological development by competitors may result in our products and product candidates or technology platforms becoming non-competitive or obsolete before we are able to recover our research and development and commercialization expenses. If we, our products and product candidates or our technology platforms do not compete effectively, it is likely to have a material adverse effect on our business, financial condition and results of operation.

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

Identifying and qualifying patients to participate in our clinical trials is critical to our success. Patient enrollment depends on many factors, including the size and nature of the patient population, eligibility criteria for the trial, the proximity of patients to clinical sites, the design of the clinical protocol, the availability of competing clinical trials, the availability of new drugs approved for the indication the clinical trial is investigating, and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies. Since some of our product candidates are focused on addressing rare diseases and conditions, there are limited patient pools available to complete our clinical trials in a timely and cost-effective manner. For example, the number of patients suffering from each of MG, ITP, PV, PF, CIDP, T-cell lymphoma (**TCL**) and AML is small and has not been established with precision. If the actual number of patients with these disorders is smaller than we anticipate, we may encounter difficulties in enrolling patients in our clinical trials, thereby delaying or preventing development and approval of our drug candidates. Even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. In addition, a limited number of patients enrolled in our clinical trials are located in Russia or Ukraine. The conflict between Russia and Ukraine (also see risk factor 2.7.4 "Global economic uncertainty and weakening product demand caused by political instability, changes in trade agreements and conflicts, such as the conflict between Russia and Ukraine, could adversely affect our business and financial performance.") may prevent their continued participation in such trials and may prevent us from enrolling new patients from such countries which, in turn, may cause delays in certain ongoing clinical trials. For example, a relevant minority of the patients in the ADDRESS trial of SC efgartigimod for PF and PV are participating in studies conducted in Ukraine or Russia. Accordingly, we expect that the conflict between Russia and Ukraine will delay our ADDRESS trials, with the timing of topline data for the ADDRESS trial of SC efgartigimod for PF and PV currently under review.

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

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

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

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

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

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

Although we maintain product liability insurance for our product candidates, the coverage of which we have extended to include the sale of VYVGART™, and we expect to expand our insurance coverage further if we obtain marketing approv-

al for any of our other product candidates, we may not be able to maintain insurance coverage at a reasonable cost or to obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We may from time to time seek orphan drug designation in the U.S. or Europe for certain indications addressed by our products and product candidates. For example, in September 2017, the FDA granted orphan drug designation for the use of VYVGART™ for gMG, in January 2019, the FDA granted orphan drug designation for the use of efgartigimod for the treatment of Primary Immune Thrombocytopenia 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 Inflammatory Demyelinating Polyneuropathy. Even if we are able to obtain orphan designation, we may not be the first to obtain marketing approval for such indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the U.S. may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the FDA or the EMA can subsequently approve the same drug with the same active moiety for the same condition if the FDA or the EMA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

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

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

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

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

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

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

2.4 Risk Factors Related to argenx's Business and Industry

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

The international biopharmaceutical and medical technology industries are subject to a high level of regulation by the FDA, the EMA, the PMDA and other comparable regulatory authorities and by other national or supra-national regulatory authorities. Applicable regulations impose substantial requirements covering nearly all aspects of our activities and the activities of our partners and licensees, notably on research and development, manufacturing, preclinical tests, clinical trials, labeling, marketing, sales, storage, record keeping, promotion and pricing of our products and product candidates.

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

Regulations differ substantially per jurisdiction and are subject to constant change. In order to market our future products in regions such as the EEA, the U.S., Asia Pacific and many other foreign jurisdictions, we must obtain separate regulatory approvals. The approval procedures vary among countries and can require additional clinical testing, and the time required to obtain approval may differ from that required to obtain approval. Moreover, clinical studies conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the EMA, the FDA or the PMDA does not ensure approval by the comparable authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the EMA, the FDA or the PMDA. There can be no assurance that our product candidates will fulfil the criteria required to obtain necessary regulatory approval to access the market. Also, at this time, we cannot guarantee or know the exact nature, precise timing and detailed costs of the efforts that will be necessary to complete the remainder of the development of our research programs and product candidates. Each of the FDA, EMA, PMDA and other comparable regulatory authorities may impose its own requirements, may discontinue an approval or revoke a license, may refuse to grant approval, or may require additional data before granting approval, notwithstanding that approval may have been granted by the FDA, EMA, PMDA or one or more other comparable foreign authority. The FDA, EMA, PMDA or other comparable regulatory authorities may also approve a product candidate for fewer or more limited indications or patient sub-segments than requested or may grant approval subject to the performance of post-marketing studies. The EMA's, the FDA's, the PMDA's or other regulatory authority's approval may be delayed, limited or denied for a number of reasons, most of which are beyond our control. Such reasons could include, among others, the production process or site not meeting the applicable requirements for the manufacture of regulated products, or the products not meeting applicable requirements for safety, purity or potency, or efficacy, during the clinical development stage or after marketing.

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

We and our collaborative partners are, or may become subject to, numerous ongoing other regulatory obligations, such as data protection, environmental, health and safety laws and restrictions on the experimental use of animals. The costs of compliance with such applicable regulations, requirements or guidelines could be substantial, and failure to comply could result in sanctions, including fines, injunctions, civil penalties, denial of applications for marketing authorization of our products, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly increase our or our collaborative partners' costs or delay the development and commercialization of our product candidates.

The time required to obtain approval by the FDA, EMA, PMDA and comparable regulatory authorities is unpredictable but typically takes many years, if obtained at all, following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market any of our product candidates, including VYVGART™ for the treatment of gMG in jurisdictions outside the U.S. and Japan or for other indications, which would significantly harm our business, results of operations and prospects. In addition, even when and if we obtain approval, regulatory authorities may approve any of our products and product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

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

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

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

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

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants, vendors and collaboration partners may engage in fraudulent conduct or other illegal activities. Misconduct by these parties could include intentional, reckless and negligent conduct, data manipulation (scientific fraud) or unauthorized activities that violate: (i) the regulations of the FDA, EMA, PMDA and other comparable regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the U.S. and in other countries; or (iv) laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, results of operations and financial condition, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other U.S. or international healthcare programs, individual imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, other sanctions, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. These risks may be particularly heightened given our lack of experience with commercialization and the rapid growth of our sales and marketing function. Furthermore, due to the highly regulated environment in which we operate and our heavy reliance on approval of our products by governmental entities and healthcare providers, reputational risks related to the misconduct or other improper behavior as described above are likely to have a bigger impact on us than on most companies operating in other industries.

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

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

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

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

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

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

We could be required to expend significant amounts of money and other resources to respond to these threats or breaches and to repair or replace information systems or networks, and could suffer financial loss or the loss of valuable confidential information. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have

a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. This risk is further increased by the growing amount of data transferred by us between Europe, China and the U.S. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely and there can be no assurance that any measures we take will prevent cyber-attacks or security breaches that could adversely affect our business.

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

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

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

Also, certain raw materials or other products necessary for the manufacture and formulation of our products and product candidates, some of which are difficult to source, are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, laboratory testing and other services related to the manufacture of our products and product candidates, and to supply various raw materials and other products. We would be unable to obtain these raw materials, other products, or services for an indeterminate period of time if any of these third parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or actions (including recalls), adverse financial developments at or affecting the supplier, failure by the supplier to comply with cGMPs, contamination, business interruptions, or labor shortages or disputes. Interruptions in the supply of these materials, products or services may result from international conflict, trade disputes or economic sanctions enacted by, or imposed on, the U.S., the European Union or any other country. In any such circumstances, we may not be able to engage a backup or alternative supplier or service provider in a timely manner or at all. This, in turn, could materially and adversely affect our ability to supply products and product candidates, which could materially and adversely affect our business, financial condition and results of operations.

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

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

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

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

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

We have relied upon and plan to continue to rely upon third parties, including licensees, independent clinical investigators and third-party CROs, to conduct our preclinical studies and clinical trials and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our partners, third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, EMA, PMDA and comparable regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we, our investigators or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA, PMDA or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Upon inspection by a given regulatory authority, such regulatory authority may determine that our clinical trials do not fully comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

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

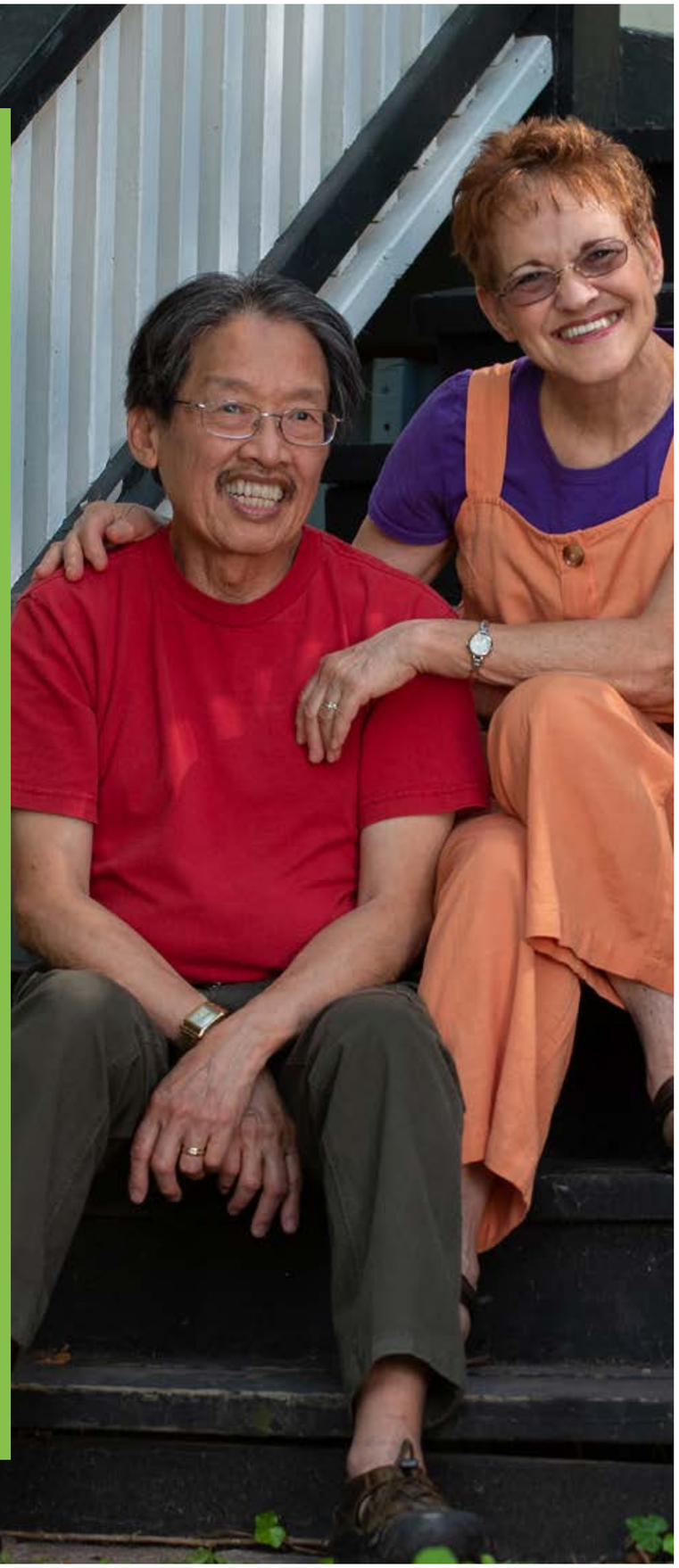
Victor & Iris

Victor and Iris Yipp Find Hope in MG*

Victor Yipp and his wife, Iris, have been an unstoppable team through the highs and lows of Victor's MG diagnosis.

Patient Story

**Paid contributor to MG United.*



Can you describe the journey to Victor's MG diagnosis?

Iris: The entire year of 2017 led up to that MG diagnosis. Victor started getting symptoms, one by one. The first one was an issue with swallowing.

Victor: The doctors thought it was a GI problem.

Iris: Yeah, but the GI treatments didn't help. Then you had double vision, so we went to the ophthalmologist.

Victor: They couldn't find anything wrong. But everything was adding up: the swallowing issue, the double vision, the inability to hold up my head…

Iris: We went to a bunch of doctors. But it was our own doctor who eventually figured it out. He had started researching MG after we came in because he'd never seen it before. But things went downhill quickly after that—the diagnosis and the hospitalization were only days apart. Victor was diagnosed on Wednesday, November 1, 2017. By Sunday he couldn't drink water and needed to go to the hospital.

I was in the hospital for 32 days.

What happened after you got out of the hospital? How did life change?

Iris: It took months for him to recover. With MG you can look fine, but you may be unable to get through the day. You have to rest. For instance, when he first got out, we got a temporary handicap parking permit. I always felt like people were going to judge us.

Victor: Because I didn't look like I needed handicap parking. I think that's the one thing many people misunderstand. You look normal, but there's a lot going on inside that people can't see.

How did you think MG would affect your future?

Iris: I didn't really think ahead, beyond dealing with the symptoms right then. We did try some MG support groups. And in one of them, there was someone in remission for about 15 years. I thought, 'Wow that would be amazing.' It gave us hope. I thought, 'You can do it Victor.'

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

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

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

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

We are, and expect to continue to be, dependent on partnerships with partners relating to the development and commercialization of our existing and future research programs and product candidates. We currently have collaborative research relationships with various pharmaceutical companies such as AbbVie, Shire, Zai Lab and with various academic and research institutions worldwide, for the development of product candidates resulting from such collaborations. We had, have and will continue to have discussions on potential partnering opportunities with various pharmaceutical companies. If we fail to enter into or maintain collaborations on reasonable terms or at all, our ability to develop our existing or future research programs and product candidates could be delayed, the commercial potential of our products could change and our costs of development and commercialization could increase.

Our dependence on collaborative partners subjects us to a number of risks, including, but not limited to the termination of the collaboration agreements with all its consequences, disagreement on the interpretation of contractual terms or no adherence or uncertainties as part of the ongoing collaboration. In addition, we may not be able to control our collaborative partners' compliance with all applicable requirements for the commercialization of our products, which could adversely affect such commercializing and the profitability of such products (also see risk factor 2.4.3 "Our employees and relevant third parties may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could have a material adverse effect on our business.").

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

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

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

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

We and our third-party suppliers may also be subject to audits by the FDA, EMA, PMDA or other comparable regulatory authorities. If any of our third-party suppliers fails to comply with cGMP or other applicable manufacturing regulations, our ability to develop and commercialize the products could suffer significant interruptions. We face risks inherent in relying on a single CMO, as any disruption, such as a fire, pandemic, natural hazards or vandalism at the CMO could significantly interrupt our manufacturing capability. Alternative production plans in place or disaster-recovery facilities available to us may not be sufficient. In case of a disruption, we may have to establish additional alternative manufacturing sources. This would require substantial investment on our part, which we may not be able to obtain on commercially acceptable terms or at all. Additionally, we may experience significant manufacturing delays as we build or locate replacement facilities and seek and obtain necessary regulatory approvals. If this occurs, we will be unable to satisfy manufacturing needs on a timely basis, if at all. Also, operating any new facilities may be more expensive than operating our current facilities. Further, business interruption insurance may not adequately compensate us for any losses that may occur, and we would have to bear the additional cost of any disruption. For these reasons, a significant disruptive event of the manufacturing facility could have drastic consequences, including placing our financial stability at risk.

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

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

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

2.6 Risk Factors Related to argenx's Intellectual Property

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

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

We cannot be certain that patents will be issued or granted with respect to applications that are currently pending. As a biopharmaceutical company our patent position is uncertain because it involves complex legal and factual considerations. The standards applied by the European Patent Office, the U.S. Patent and Trademark Office (**USPTO**) and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biopharmaceutical patents. Consequently, patents may not issue from our pending patent applications. As such, we do not know the degree of future protection that we will have on our proprietary products and technology. The scope of patent protection that the European Patent Office and the USPTO will grant with respect to the antibodies in our antibodies product pipeline is uncertain. It is possible that the European Patent Office and the USPTO will not allow broad antibody claims that cover antibodies closely related to our products and product candidates as well as the specific antibody. As a result, upon receipt of EMA or FDA approval, competitors may be free to market antibodies almost identical to ours, including biosimilar antibodies, thereby decreasing our market potential. However, a competitor cannot submit to the FDA an application for a biosimilar product based on one of our products until four years following the date of approval of our "reference product," and the FDA may not approve such a biosimilar product until twelve years from the date on which the reference product was approved.

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

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

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

To protect our competitive position, we may from time to time need to resort to litigation in order to enforce or defend any patents or other intellectual property rights owned by or licensed to us, or to determine or challenge the scope or validity of patents or other intellectual property rights of third parties. Enforcement of intellectual property rights is difficult, unpredictable and expensive, and many of our or our licensors' or collaboration partners' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaboration partners can. Accordingly, despite our or our licensors' or collaboration partners' efforts, we or our licensors or collaboration partners may not prevent third parties from infringing upon or misappropriating intellectual property rights we own or control, particularly in countries where the laws may not protect those rights as fully as in the European Union and the U.S. We may fail in enforcing our rights, in which case our competitors may be permitted to use our technology without being required to pay us any license fees and/or royalties. In addition, litiga-

tion involving our patents carries the risk that one or more of our patents will be held invalid (in whole or in part, on a claim-by-claim basis) or held unenforceable. Such an adverse court ruling could allow third parties to commercialize our products or use our SIMPLE Antibody™, NHance® and ABDEG™ platform technologies, and then compete directly with us, without payment to us.

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

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

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

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

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

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

Any of these events, even if we were to ultimately prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2.7 Risk Factors Related to argenx's Organization and Operations

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

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

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

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

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

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

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

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

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

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

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

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

The conflict between Russia and Ukraine increased recruitment costs for our ADDRESS trial of SC efgartigimod for PF and PV and is expected to cause delays in our ADDRESS trial. In addition, the sanctions imposed by many countries, ongoing developments and uncertainty related to the conflict between Russia and Ukraine could adversely affect us in other ways.

For example, it could lead to increasing manufacturing costs for our products by causing disruptions in the supply chain, including as a result of transportation restrictions, increased costs of raw materials, production costs as well as having an adverse effect on the availability of materials. The conflict between Russia and Ukraine may also result in declines in the global equity and debt capital markets, limiting our ability to access such markets to obtain financing to conduct our operations and growth.

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

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

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

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

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

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

Demand for our products and our operating costs may be negatively impacted by adverse conditions in the U.S., the European Union and global economies. A number of factors may contribute to a decline in economic conditions, including, but not limited to, rising government debt levels, fiscal and central bank policy shifts, the withdrawal of government interventions into the financial markets, changing consumer spending patterns, and changing expectations for inflation and deflation which may impact interest rates. For example, at its January 2022 the Federal Open Market Committee Meeting, the United States Federal Reserve Bank indicated it expects to raise benchmark interest rates in 2022, partially in response to increasing inflation and a strong labor market. Increased interest rates may decrease demand for our products, even as inflation places pressure on consumer spending, borrowing and saving habits as consumers evaluate their prospects for future income growth and employment opportunities in the current economic environment, and as borrowers face uncertainty about the impact of rising prices on their ability to repay a loan. A change in demand for our products and any steps we may take to mitigate such change could impact our overall growth. Furthermore, inflationary and other economic pressure could negatively affect our business, financial condition, results of operations, cash flows and future prospects.

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

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

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

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

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

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

3

Non-financial Reporting Requirements

Contents

3 Non-financial Reporting Requirements

The European Directive 2014/95/EU dated October 22, 2014 (**NFRD**) imposes on public-interest entities which are large undertakings with more than 500 employees, the obligation to publish non-financial information including information on environmental, social and governance matters (**ESG**), diversity, respect for human rights and on anti-corruption and bribery matters. The NFRD has been fully implemented in The Netherlands by the Act implementing the Directive 2014/95/EU dated September 28, 2016, the Decree disclosure of diversity policy dated December 31, 2016 and the Decree on disclosure of non-financial information dated March 14, 2017. In the financial year 2021 we have for the first time crossed the 500 employee threshold and have become subject to reporting requirements under NFRD.

In addition, as a public interest entity, we became subject to the EU Taxonomy Climate Delegated Act (EU) 2021/2139 (the Climate Delegated Act) reporting requirements.

In this chapter 3, we make all disclosures required for our compliance with NFRD and the Climate Delegated Act, and ancillary legislation and guidelines applicable to us.

In addition to the non-financial disclosures made in this Universal Registration Document, we plan to publish a separate and dedicated report on ESG annually, starting in 2022, which will give more context as well as additional, voluntary disclosures on ESG and related subjects.

3.1 Disclosures pursuant to the EU Non-Financial Reporting Directive

Social and employee matters	
Subtopic	Disclosure
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.
A description of the policies pursued, including due diligence processes	Our Code of Business Conduct and Ethics (**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 is an enabler to 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. All employees are trained annually on our Code of Conduct, and accepting, and committing to, the contents thereof is expected of all newcomers to argenx. 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 which was revised in 2021 to be compliant with the new EU Whistleblower directive.
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 Universal Registration Document, for the financial year ended December 31, 2021, we have not identified any material breaches of our Code of Conduct in relation to social or employee matters.
Principle 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.
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 argenx' policy confidentially or anonymously (to the extent allowed by law). We have in 2021 revised our existing Whistleblower Policy into our new Speak-up Policy compliant 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 law (EU Whistleblower Directive), which policies (jointly our Speak-up Policy) enables and encourages our employees to speak up and report any suspected violation of our Code of Conduct, and to protect them from retaliation. We have set-up a specific helpline reachable through different channels including by phone, also anonymously, to report 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 (peer 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 Universal Registration Document, for the financial year ended December 31, 2021, 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 financial year 2021 is 4.28% and our involuntary employee turnover rate for the financial year 2021 was 1.03%, both numbers we believe to be below industry averages.

Environmental matters	
Subtopic	Disclosure
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 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, or AAALAC, 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.
The outcome of those policies	At the date of this Universal Registration Document, for the financial year ended December 31, 2021, 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.
Principle 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 trainings 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. We train all personnel involved in research activities with live animals, on our Animal Welfare Policy. 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 environmental 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 argenx' policy confidentially or anonymously (to the extent allowed by law), including in relation to violations of our Code of Conduct on environmental matters or in relation to violations of our Animal Welfare Policy. Our Speak-up Policy enables and encourages our employees to speak up and report any suspected violation of our Code of Conduct, and to protect them from retaliation. We have set-up a specific helpline reachable through different channels including by phone, also anonymously, to report suspected potential violations. Also to mitigate the risks of non-compliance with our Code of Conduct in relation to environmental 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.
Non-financial key performance indicators	At the date of this Universal Registration Document, for the financial year ended December 31, 2021, 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.

Relevant matters with respect to human rights	
Subtopic	Disclosure
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.
The outcome of those policies	For the financial year ending December 31, 2021, there have been no alleged breaches of our Code of Conduct on the topics of human rights or alleged forced labor or child labor.
Principle 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 argenx' 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. Our Speak-up Policy enables and encourages our employees to speak up and report any suspected violation of our Code of Conduct, and to protect them from retaliation. We have set-up a specific helpline reachable through different channels including by phone, also anonymously, to report suspected potential violations. Also to mitigate the risks of non-compliance with our Code of Conduct in relation to human rights issues, 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.
Non-financial key performance indicators	For the financial year ending 31 December 2021, there have been 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	
Subtopic	Disclosure
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.

	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	At the date of this Universal Registration Document, for the financial year ended December 31, 2021, we have not identified any breaches of our Code of Conduct in relation to anti-corruption or anti-bribery matters.
Principle 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. 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 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, we have established the argenx COMPASS Helpline, where our employees can raise any concerns they may have regarding potential violations of argenx' 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. Our Speak-up Policy enables and encourages our employees to speak up and report any suspected violation of our Code of Conduct, and to protect them from retaliation. We have set-up a specific helpline reachable through different channels including by phone, also anonymously, to report suspected potential violations. Also to mitigate the risks of non-compliance with our Code of Conduct in relation to anti-bribery and anti-corruption, 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.
Non-financial key performance indicators	At the date of this Universal Registration Document, for the financial year ended December 31, 2021, we have not identified any breaches of our Code of Conduct in relation to anti-corruption or anti-bribery matters.

Insight into our diversity, equity and inclusion policy and practices	
Subtopic	Disclosure
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. 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 and we expect to report on specific initiatives taken in this regard, in the ESG reports expect to publish annually, starting in 2022.
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).
The outcome of those policies, results of the Diversity, Equity and Inclusion Policy	As at December 31, 2021, our Board of Directors consisted of 8 directors, including 1 executive director and 7 non-executive directors. The full board contained 6 male directors (including 1 executive director) and 2 female directors (non-executive), translating into a 75% male / 25% female balance for our full board of directors and a 71.4% male / 28.6% female balance for our non-executive directors. As at December 31, 2021, our company leadership team consisted of 23 persons of whom 14 male (60%) and 9 female (40%) persons. 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 high-impact across the organization, leading a global and cross-functional team and having a global reach. As at December 31, 2021, 58% of the members of our workforce who disclosed their gender identity, were female, and 42% male.

3.2 EU Environmental Taxonomy

We have examined all taxonomy-eligible economic activities listed in the EU Taxonomy Climate Delegated Act (EU) 2021/2139 (the **Climate Delegated Act**) based on our activities as a biopharmaceutical group. 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 or climate change adaption. The sectors covered include energy, selected manufacturing activities, transport and buildings.

Companies are required to identify if their activities are eligible under the EU Taxonomy Regulation (EU) 2020/852. Our main activity is NACE 72.11 – Research and experimental development on biotechnology. After a thorough review involving all relevant divisions and functions, we concluded that our core economic activities are not covered by the Climate Delegated Act and consequently are taxonomy-non-eligible.

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. Therefore, they are not reported as taxonomy-eligible activities and not included in our turnover key performance indicators (**KPI**) as they are not generating external turnover on a standalone basis. We will continue to monitor any future reporting obligations and their impact.

The KPIs under the Climate Delegated Act include the turnover KPI, the capital expenditure (Capex) KPI and the operating expenditure (Opex) KPI. For the reporting period 2021, the KPIs have to be disclosed in relation to taxonomy-eligible economic activities and taxonomy-non-eligible economic activities (Art. 10 (2) of the Art. 8 Delegated Act). As our economic activities as a biopharmaceutical group are not covered by the Climate Delegated Act, the share of taxonomy-eligible economic activities in our total turnover is 0% and – consequently – the related Capex and Opex are also 0%. Accordingly, the share of taxonomy non-eligible economic activities is 100% for all three KPIs.

Corporate Governance

Contents

4 Corporate Governance

4.1 Dutch Corporate Governance Code, "Comply or Explain"

As a Dutch company, we are subject to the Dutch Corporate Governance Code. A copy of the Dutch Corporate Governance Code can be found on www.mccg.nl. The Dutch Corporate Governance Code 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 argenx's objectives: employees, shareholders and other lenders, suppliers, customers and other stakeholders. Our Board of Directors has responsibility for weighing up these interests, generally with a view to ensuring the continuity of the company and its subsidiaries, as the company seeks 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 Dutch Corporate Governance Code 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 Dutch Corporate Governance Code in their annual report and, where it does not comply with them, why and to what extent it deviates from them.

We acknowledge the importance of good corporate governance and we fully endorse the underlying principles of the Dutch Corporate Governance Code, which is reflected in a policy that complies with the best practice provisions as stated in the Dutch Corporate Governance Code (the **Board By-Laws**). The Board By-Laws are available on our website (www.argenx.com). However, we do not comply with or 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 General Meeting in 2021.

- We do not comply with best practice provisions 3.1.2 under vi of the Dutch Corporate Governance Code, which states that 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, restricted stock units vest in four equal tranches, which means that one fourth of the restricted stock units granted are settled at each anniversary of the date of granting, and no lock-up period applies to any shares acquired at such settlement. 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 staff. 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, options cannot be exercised by our directors in the first three years after the date of granting and the four-year vesting period of the restricted stock units ensures that a restricted stock unit package granted cannot be fully settled within four years after the grant date. In addition, under our previous option plans, although options could be exercised within the first three years after the date of grant of those options in accordance with the then applicable vesting scheme, until the date of this Universal Registration Document, none of the directors have done so. The Equity Incentive Plan is regularly reviewed by the Board of Directors and the 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 if the Equity Incentive Plan, including the type, size and conditions of grants thereunder, is sufficiently competitive and as such can support our ability to attract and retain talent. In 2021, our Board of Directors has amended our Equity Incentive Plan in line with our updated remuneration policy, adding specifically the granting of restricted stock units to the equity incentive scheme and including the aforementioned vesting schemes. We currently do not expect to implement trading restrictions for our directors that would bring us in full compliance with the Dutch Corporate Governance in this respect. 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 3.1.2. We currently do not envision to change our practice in this respect.
- We do not comply with best practice provision 3.2.3. of the Dutch Corporate Governance Code, which requires that 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 may become payable by argenx to our Chief Executive Officer. 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.
- We do not comply with best practice provision 3.3.2. of the Dutch Corporate Governance Code, which requires that non-executive directors will 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. 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 conscious and well-considered deviation from the Dutch Corporate Governance Code 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. We currently do not envision to change our practice in this respect.

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

4.2 Management Structure

4.2.1 General

We have a one-tier board structure consisting of executive and non-executive directors, and a senior management team 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 of 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 needs to decide on. In addition to being present to meetings from time to time, regular contact (face to face or via electronic means) is kept between the members of the Board of Directors and its committees and the members of the senior management team as well as other senior leaders in the organization.

Set out below is a summary of certain provisions of Dutch corporate law as at the date of this Universal Registration Document, as well as a summary of relevant information concerning our Board of Directors and certain provisions of the 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 Universal Registration Document and 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.

4.2.2 Statement of the Board of Directors

Responsibilities for the Financial Statements and Management Report
In accordance with Article 5:25c(2)(c) of the DFSA, the Board of Directors hereby certifies that, to the best of our knowledge, the consolidated financial statements of argenx SE as of December 31, 2021, prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the European Union, 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 Universal Registration Document
The Board of Directors declares that the information contained in the Universal Registration Document, including the consolidated financial statements of argenx SE as of December 31, 2021 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 Universal Registration Document.

In Control Statement
Our Board of Directors is responsible for the oversight of our risk management activities and has delegated to the audit and compliance committee the responsibility to assist our Board of Directors in this task. 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 4.5 “Risk Appetite & Control” for further information on our risk appetite and control.

4.2.3 Board of Directors

Responsibilities
Under Dutch law (Section 2:129 paragraph 1 of the 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 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 the management of argenx and providing the executive director(s) with advice. In addition, both the executive director(s) and the non-executive directors must perform such duties as are 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 be allocated the tasks of: (i) serving as chairperson of our Board of Directors; (ii) determining the remuneration of an executive director; or (iii) nominating 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. As a principle 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 (the **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 the General Meeting for a period of four years. In accordance with best practice principle 2.2.1 of the Dutch Corporate Governance Code, 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 Dutch Corporate Governance Code, non-executive directors are appointed for a period of four years and may subsequently be re-appointed for another four-year period. The non-executive director 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 directors are appointed as either an executive director or as a non-executive director by the shareholders at the General Meeting. Our Board of Directors designates one executive director as Chief Executive Officer. In addition, the Board of Directors may grant other titles to executive directors. Our Board of Directors 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 independent directors on our Board of Directors, except that our audit and compliance committee is required to consist fully of independent directors, subject to certain phase-in schedules. 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 Exchange Act and the applicable rules of the Nasdaq Stock Market and of the Dutch Corporate Governance Code. 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 Dutch Corporate Governance Code requires that the composition of the 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. At the date of this Universal Registration Document, all non-executive directors meet the independence criteria contained in the Dutch Corporate Governance Code. 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 Dutch Corporate Governance Code. Our Board of Directors has consequently also determined that all members of our committees are independent under the applicable rules of the Dutch Corporate Governance Code.

As of the date of this Universal Registration Document (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 the 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 the general meeting.

Diversity
We value diversity as a way of recognizing and valuing the differences between individuals to come to the most efficient and effective way to achieve our strategic objectives. For our Board of Directors, this means that when making recommendations to the general meeting for the (re-)appointment of directors, the board will aim for a diverse composition in terms of such factors as gender and age, in accordance with our diversity policy as may be in force from time to time. Under Dutch law reporting rules, argenx will be required to address diversity of our Board of Directors in its annual report or in the report of the Board of Directors (bestuursverslag): (i) composition of the Board of Directors by gender; (ii) objectives of the diversity policy; (iii) description of how the diversity policy is being implemented and the results thereof and (iv) if there is no diversity policy, this should be explained.

On January 1, 2022, new legislation entered into force, requiring "large Dutch companies" to set an 'appropriate and ambitious' target for their management board, supervisory board and senior executives (the latter as determined by the company). If a company has adopted a one-tier board structure, the appropriate and ambitious target applies to both the executive and non-executive directors. The legislation is based on a "comply or explain" principle. Accordingly, we will be required to disclose in our report of the Board of Directors whether or not we are in compliance with the self-imposed target. In addition, within ten months of the end of the financial year, we will need to report to the *Sociaal-Economische Raad* (SER) whether or not we have complied with the self-imposed target.

Board Diversity Matrix (as of the date of this Universal registration Document)

Country of Principal Executive Offices	The Netherlands			
Foreign Private Issuer	Yes			
Disclosure Prohibited by Dutch Law	No			
Total Number of Directors	7			
Gender: Number of Directors	Female 1	Male 6	Non-Binary 0	Did Not Disclose Gender 0

Demographic Background Categories	**Number of Directors in Each Demographic Category**
Underrepresented individual in home country jurisdiction	1
LGTBQ+	0
Did not disclose demographic background	6

* We had two female members of our Board of Directors as of December 31, 2021. However, on March 3, 2022, Yvonne Greenstreet stepped down from our Board of Directors due to time constraints following her appointment as Chief Executive Officer of Alnylam. As a result, we have one female member of our Board of Directors as of the date of this Universal Registration Document.

Our policy is that we will balance our Board of Directors in terms of gender, age, background and nationality as much as reasonably possible while still having our board 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, irrespective of age, background, nationality and gender, who make a balanced panel of directors 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. Considering the aforementioned and the specialist nature of our business, we will actively seek to further improve diversity on our board if and when proposing new appointments to our Board of Directors, whilst acknowledging that age, gender and nationality are important, but not the only factors relevant for the ultimate decision to select a board member. We have set ourselves the target to over time achieve an equal gender balance in our Board of Directors, and we will report on our progress annually in our ESG report.

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 will meet at least once every three months to discuss the state of affairs within the company and the expected developments.
Under the 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 and the Board By-Laws 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.

In exceptional cases, if the urgent necessity and the interests of argenx require this, resolutions of our Board of Directors may also be adopted by unanimous written approval of all directors in office. A director may issue a proxy for a specific board meeting to another director in writing.

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 Dutch Corporate Governance Code, our non-executive directors can set up specialized committees to analyze specific issues and advise the non-executive directors on those issues.

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 Dutch Corporate Governance code, the Exchange Act, the exchange on which the ordinary shares and the ADS are listed and 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 argenx.

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: Werner Lanthaler (chairperson), Peter K. M. Verhaeghe, Anthony A. Rosenberg and James M. Daly. Our Board of Directors has established that Werner Lanthaler 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 governed by a charter that complies with Nasdaq listing rules and the Dutch Corporate Governance Code. Our audit and compliance committee is responsible for, among other things, establishing methods and procedures for supervising, and where necessary requiring improvements of, our financial reporting, 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. Our audit and compliance committee meets at least once a year with our independent auditor.

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 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 Dutch Corporate Governance Code. Our remuneration and nomination committee consists of four members: J. Donald deBethizy (chairperson), Peter K. M. Verhaeghe, Werner Lanthaler and Yvonne Greenstreet.

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

- regularly reviewing the remuneration policy 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 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.

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 three members: David L. Lacey (chairperson), J. Donald deBethizy and Pamela Klein. J. Donald deBethizy and Pamela Klein are members of our Board of Directors. David L. Lacey resigned from our Board of Directors per May 11, 2021, but continues to serve as an advisor on the Research and Development Committee. Ad-hoc participants to the committee meetings furthermore 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.

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 the strategic reviews. 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.

Commercial committee
The 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 Universal Registration Document, the commercial committee consists of two permanent members: James M. Daly (chairperson) and A.A. Rosenberg.

The commercial committee is responsible for, among other things:

- 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 reports regularly to our Board of Directors on the outcome of its strategic reviews.

4.2.4 Non-Executive Directors

Our Board of Directors as at 31 December 2021 comprised the following seven 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 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 (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 serves on the board of directors of Participatiemaatschappij Vlaanderen (PMV) 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 holds a degree in law (J.D.) from the University of Leuven and an LLM degree from Harvard Law School.

Dr. Werner Lanthaler

Dr. Werner Lanthaler has served as a member of our Board of Directors since July 2014. Dr. Lanthaler is the chief executive officer 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.

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 and Innovent LLC, board and CEO coaching consultancies. Previously, Dr. deBethizy served as president and chief executive officer 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 chief executive officer of Targacept, Inc., a U.S. biotechnology company listed on Nasdaq. He currently serves on the supervisory boards of Albumedix A/S, Lophora ApS Newron Pharmaceuticals SpA, Noxxon Pharma NV and AG, Rigontec GmbH and Proterris, Inc. From May 2013 to November 2014, he served as executive chairman of Contera Pharma ApS, and from July 2015 to November 2017, he served as chairman of Rigotec GmbH. He previously served on the boards of Asceneuron SA, Serendex Pharmaceuticals A/S, Enbiotix Inc., Targacept Inc., LigoCyte Pharmaceuticals Inc 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. He has been a Diplomate of the American Board of Toxicology.

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 several board of director's including F-Star Therapeutics, Jiya Acquisition Corps, I-Mab and Patry's; as well as various scientific advisor boards. Previously, Dr. Klein spent seven years at the National Cancer Institute as Research Director of the NCI-Navy Breast Center, after which she joined Genentech and was VP, Development until 2001. She served as Chief Medical Officer for Intellikine which was acquired by Takeda. She was previously Vice President, Development for Genentech. 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.

Msc. A. A. Rosenberg

Msc. A. 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. 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 currently serves on the boards of directors of SiO2 Material Science, Oculis SA (chairman) and Cullinan Oncology (chairman), and 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 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, 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 Therapeutics, Inc., Bellicum Pharmaceuticals, Inc. and Madrigal Pharmaceuticals, all Nasdaq-listed companies. Mr. Daly holds a Bachelor in Science and a Master in Business Administration from the University at Buffalo, State University of New York.

Yvonne Greenstreet

Dr. Greenstreet has served as a member of our Board of Directors since May 2021. She was appointed Chief Executive Officer of Alnylam Pharmaceuticals effective January 1, 2022 and was serving as President and Chief Operating Officer at Alnylam Pharmaceuticals before. Dr. Greenstreet has more than 25 years of experience in the Biopharmaceutical industry, driving strategy and innovation, bringing transformative medicines to patients and building successful businesses in the U.S., Europe and globally.

Dr. Greenstreet serves on the board of directors of Pacira Pharmaceuticals, American Funds, the Scientific Advisory Committee of the Bill and Melinda Gates Foundation and is a member of the Discovery Council of Harvard Medical School. Between 2011 and 2013, Dr. Greenstreet was Senior Vice President and Head of Medicines Development at Pfizer serving on the executive team leading a rapidly growing $16 billion division. Prior to Pfizer, she was at GlaxoSmithKline plc for 18 years, where she was Senior Vice President and Chief of Strategy for Research and Development.

Dr. Greenstreet had previously been in various positions of increasing responsibility at GSK, including Senior Vice President for Medicines Development and Chief Medical Officer for Europe. Dr. Greenstreet is trained as a physician and earned her medical degree from Leeds University in the United Kingdom and her MBA degree from INSEAD, France.

On March 3, 2022, Dr. Greenstreet stepped down from her position as member of our Board of Directors due to time constraints following her appointment as Chief Executive Officer at Alnylam.

The following table sets forth certain information with respect to the current non-executive members of our Board of Directors, including their ages, as at December 31, 2021.

Name	Age	Gender	Postion	Nationality	Date of Initial Appointment	Date of last (re-) Appointment	Term Expiration
Peter K. M. Verhaeghe	63	M	Non-Executive Director (chairperson)	Belgium	October 15, 2008	May 8, 2018	2022
Werner Lanthaler	53	M	Non-Executive Director (vice-chairperson)	Austria	July 9, 2014	May 8, 2018	2022
J. Donald deBethizy	71	M	Non-Executive Director	U.S.	May 13, 2015	May 7, 2019	2023
Pamela Klein	60	F	Non-Executive Director	U.S.	April 28, 2016	May 12, 2020	2024
Anthony A. Rosenberg	68	M	Non-Executive Director	UK	April 26, 2017	May 11, 2021	2025
James M. Daly	60	M	Non-Executive Director	U.S.	May 8, 2018	May 8, 2018	2022
Yvonne Greenstreet[1]	59	F	Non-executive director	UK	May 11, 2021	May 11, 2021	2025

(1) On March 3, 2022, Yvonne Greenstreet stepped down from her position as member of our Board of Directors.

The address for our non-executive directors is our registered office, Willemstraat 5, 4811 AH, Breda, the Netherlands.

Peter K.M. Verhaeghe, Werner Lanthaler and James M. Daly are expected to be nominated for re-appointment at the General Meeting to be held in 2022.

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 Universal Registration Document, other than argenx or our subsidiaries:[12]

NAME	CURRENT	PAST
Peter K. M. Verhaeghe	VVGB Advocaten – Avocats	PharmaNeuroBoost NV
	Haretis SA	Biocartis SA
	Participatiemaatschappij Vlaanderen (PMV) 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	Evotec SE	Bioxell SpA
	AC Immune SA	Pantec Biosolutions AG
J. Donald deBethizy	White City Consulting ApS	Rigontec GmbH
	Albumedix A/S	Noxxon Pharma NV and AG
	Newron Pharmaceuticals SpA	
	Protteris Inc.	
	Lophora ApS	
	Saniona AB	
	Albumin Holdings ApS	
	Innovent LLC	
Pamela Klein	PMK BioResearch	Olema Oncology
	Patrys Limited	
	I-Mab Biopharma	
	F-Star Therapeutics, Inc.	
	Jiya Acquisition Corp.	
Anthony A. Rosenberg	Cullinan Oncology Inc.	Radius Health, Inc.
	Oculis SA	TriNetX, Inc.
	SiO2 Material Science	Clinical Ink, Inc.
	TR Advisory Services GmbH	iOmx Therapeutics AG
		MPM Capital
James M. Daly	Acadia Pharmaceuticals Inc.	Chimerix, Inc.
	Halozyme Therapeutics, Inc.	
	Bellicum Pharmaceuticals, Inc.	
	Madrigal Pharmaceuticals	
Yvonne Greenstreet[1]	Alnylam Pharmaceuticals, Inc.	–
	Pacira Pharmaceuticals, Inc.	
	American Fund	

(1) On March 3, 2022, Yvonne Greenstreet stepped down from her position as member of our Board of Directors.

4.2.5 Senior Management

Our senior management team acts as our executive management. Of these persons, only our Chief Executive Officer, Mr. Tim Van Hauwermeiren, is part of our Board of Directors as executive director. Our senior management team comprised of the following persons as at December 31, 2021 and as at the date of this URD:

Tim Van Hauwermeiren

Tim Van Hauwermeiren co-founded our Company in 2008 and has served as our Chief Executive Officer 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 B. Sc. and M. Sc. 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 Pharmaceuticals and Aelin Therapeutics where he is chairman.

Keith Woods

Keith Woods has served as our Chief Operating Officer since April 2018. 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., 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 over a span of 20 years. Keith Woods holds a B.S. in marketing from Florida State University.

Karl Gubitz

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

Within Pfizer, 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 in 2003, Mr. Gubitz held various management roles at PricewaterhouseCoopers.

He holds an M.B.A. from Henley Management College in the United Kingdom, 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 an M. Sc. in biochemistry from the Higher Professional Education for Laboratory Technicians (Oss, the Netherlands) and a M. Sc. in chemistry from the Institute of Technology (Rotterdam, the Netherlands) and a Ph. D. in molecular immunology from Maastricht University.

Dirk Beeusaert

Dirk Beeusaert has served as General Counsel of argenx since 2017. He has 20 years of experience in corporate governance and as general counsel of a listed company. Mr. Beeusaert worked in various roles from February 1996 to July 2016 for Gimv NV, a European private equity company listed on Euronext Brussels, including chief legal officer from January 2001 to 2006, and general counsel from 2006 to July 2016, where he was co-responsible for operations and corporate governance.

He currently serves on the boards of Cubigo NV and The Fourth Law NV. Dirk holds a Bachelor of Law, Master of Law from Ghent University and an MBA in fiscal studies and accounting research, tax and accounting from Vlerick Leuven-Gent Management School.

Mr. Beeusaert has retired per December 31, 2021 and has since been succeeded by Malini Moorthy as from February 14, 2022.

Malini Moorthy

Malini Moorthy joined argenx as General Counsel in 2022. She has over 25 years of legal experience with extensive experience in the biopharmaceutical and medical device sectors, including as senior vice president & chief deputy general counsel, legal, compliance & government affairs at Medtronic, vice president & associate general counsel, head of global litigation & investigations at Bayer Corporation, vice president & assistant general counsel, head of civil litigation at Pfizer Inc. Malini Moorthy began her career as a law firm associate, first with McCarthy Tétrault and Genest Murray Desbrisay Lamek in Toronto, Canada and then Salans (now Dentons) 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.

Wim Parys

Wim Parys joined argenx as Chief Medical Officer in 2019. He has 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, he was the R&D head of the newly established Global Public Health group at Janssen (Johnson & Johnson) responsible for a portfolio including programs in HIV (developing first long-acting therapy), TB, dengue fever and malaria. Before this, Mr. Parys was the head of development of the infectious disease therapeutic area of Janssen and Tibotec where he developed and launched innovative drugs for HIV (Prezista™, Intelence™ and Edurant™), Hepatitis C (Incivo™, Olysio™/Sovriad™), and TB ((Sirturo™).

He started his career within the Johnson & Johnson organization at the Janssen Research Foundation in Belgium where he led the R&D team developing galantamine (Reminyl™/Razadyne™) for Alzheimer's disease. He obtained his medical degree from the Katholieke Universiteit in Leuven, Belgium and worked in private practice for nine years prior to joining industry. Mr. Parys will retire with effect from March 31, 2022 and will be succeeded by Luc Truyen as of April 1, 2022.

Luc Truyen

Luc Truyen joined argenx at the end of September 2021. 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 R&D and chief medical officer of Janssen Alzheimer Immunotherapy, an internal spin-out from Johnson & Johnson. Dr. Truyen holds an M.D. and Ph.D. in Neurology from the University of Antwerp.

Luc Truyen will succeed Wim Parys with effect as of April 1, 2022 as a member of our senior management team.

Arjen Lemmen

Arjen Lemmen joined argenx in 2016 and serves as Vice President of Corporate Development & Strategy at argenx since 2019. He has successfully executed several transactions including a number of programs within the Immunology Innovation Program and the strategic collaboration with Janssen for cusatuzumab.

Prior to joining argenx, Mr. Lemmen served as a corporate finance specialist at Kempen & Co focusing on M&A, equity capital markets and strategic advisory transactions in the European life sciences industry. He holds a B.Sc. 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 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, Takeda Global Research and Development (TGRD) and Astellas Pharmaceuticals. Ms. Wilk holds a joint B.Sc. in Pharmacology and Biochemistry and is a member of Research Quality Association (MRQA).

The following table sets forth certain information with respect to the members of our senior management, including their ages, as at December 31, 2021 and as at the date of this URD:

Name	Age	Postion	Nationality	Date of first employment/engagement
Tim Van Hauwermeiren	49	Chief Executive Officer and Executive Director	Belgium	July 15, 2008[1]
Keith Woods	54	Chief Operating Officer	U.S.	April 5, 2018
Karl Gubitz	52	Chief Financial Officer	Germany	June 1, 2021
Prof. Hans de Haard	62	Chief Scientific Officer	The Netherlands	July 1, 2008
Dirk Beeusaert[2]	57	General Counsel	Belgium	April 1, 2017
Malini Moorthy[2]	52	General Counsel	Canada	February 14, 2022
Wim Parys[3]	62	Chief Medical Officer	Belgium	July 1, 2019
Arjen Lemmen	37	Vice-President Corporate Development & Strategy	The Netherlands	May 1, 2016
Andria Wilk	49	Global Head of Quality	UK	January 13, 2020

(1) Tim Van Hauwermeiren has been a member of our Board of Directors since July 9, 2014.
(2) Dirk Beeusaert has retired per December 31, 2021 and has since been succeeded by Malini Moorthy as from February 14, 2022.
(3) Wim Parys will retire with effect from March 31, 2022 and will be succeeded by Luc Truyen as of 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 current members of our senior management 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 Universal Registration Document, other than argenx or our subsidiaries:

Name	Current	Past
Tim Van Hauwermeiren	Iteos NV	–
	Aelin Therapeutics	
Keith Woods	–	
Karl Gubitz	–	
Prof. Hans de Haard	–	–
Dirk Beeusaert [1]	Cubigo NV	Gimv NV (and group companies of Gimv NV)
	The Fourth Law NV	TINC NV
		Pragma Capital SAS
		Grandeco NV
		DG Infra+ NV
		Finimmo NV
		CapMan plc
Malini Moorthy[1]	–	–
Wim Parys[2]	–	–
Arjen Lemmen	–	–
Andria Wilk	–	Lundbeck A/S

(1) Mr. Beeusaert has retired per December 31, 2021 and has since been succeeded by Malini Moorthy as from February 14, 2022.
(2) Mr. Parys will retire with effect from March 31, 2022 and will be succeeded by Luc Truyen as of April 1, 2022.

4.2.6 Confirmation of No Past Offenses

As of the date of this Universal Registration Document 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.

4.2.7 Liability of Board and Senior Management Members

Under Dutch law (Section 2:138 of the DCC), members of our Board of Directors may be liable to us for damages in the event of improper or negligent performance of their duties. They may be jointly and severally liable for damages to us and third parties for infringement of the Articles of Association or certain provisions of the Dutch Civil Code (**DCC**). In certain circumstances, they may also incur additional specific civil and criminal liabilities.

The liability of members of our Board of Directors and senior management team is covered by a directors' and officers' liability insurance policy. This policy contains customary limitations and exclusions, such as willful misconduct or intentional recklessness (*opzet of bewuste roekeloosheid*). In addition, according to article 15 of our Articles of Association, we will indemnify our directors against liabilities, claims, judgements, fines and penalties in relation to acts or omissions in or related to his or her capacity as director.

4.2.8 Conflict-of-Interest Transactions

Directors will immediately report any (potential) direct or indirect personal interest in a matter which is conflicting 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 and will 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. 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 has a conflict of interest in the matter being discussed. If for this reason no resolution can be taken by our Board of Directors as a whole, the shareholders at a General Meeting 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 stipulates that material transactions with related parties that are (a) not entered into in the ordinary course of business of argenx or (b) that are not concluded on normal market terms, require approval of the board of directors. 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. Directors that are involved in the related party transaction are prohibited from participating in the deliberations and voting on the matter. Such 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 Market Abuse Regulation ((EU) No. 596/2014) (the **Market Abuse Regulation** or **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 in itself non-material, but which are entered into with the same related party during the same financial year, are jointly considered 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.

4.2.9 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 at www.argenx.com. 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.

4.3 Report of the Non-Executive Directors

4.3.1 Meetings

Our Board of Directors had eight formal meetings in the course of 2021. The meetings were held in the months March (twice), April, May, July, October, November 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 paragraphs 4.3.5 "Report Audit and Compliance Committee" to 4.3.8 "Report Commercial Committee" below for the separate reports of the committees).

All Board of Director meetings and almost all committee meetings were also attended by Mr. Tim 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.

4.3.2 Attendance Record Board of Director Meetings

In 2021, eight Board of Directors meetings were held. The meeting attendance rate for our directors is set out in the table on the next page.

Name	Number of meetings attended in 2021 since appointment	Attendance %
Peter K. M. Verhaeghe (chairperson)	8/8	100%
Werner Lanthaler	7/8	87.5%
J. Donald deBethizy	8/8	100%
Pamela Klein	8/8	100%
Anthony A. Rosenberg	8/8	100%
James M. Daly	8/8	100%
Yvonne Greenstreet[1]	5/5	100%
David L. Lacey[1]	3/3	100%

(1) Yvonne Greenstreet replaced David L. Lacey as a non-executive director after he resigned from our Board of Directors per May 11, 2021. Until his resignation, David L. Lacey attended as a non-executive director three out of the three Board of Directors meetings held so far that year.

In 2021, four 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 four meetings were attended by all non-executive directors appointed at such time.

Name	Number of meetings attended in 2021 since appointment	Attendance %
Peter K. M. Verhaeghe	4/4	100%
Werner Lanthaler	4/4	100%
J. Donald deBethizy	4/4	100%
Pamela Klein	4/4	100%
Anthony A. Rosenberg	4/4	100%
James M. Daly	4/4	100%
Yvonne Greenstreet[1]	2/2	100%
David L. Lacey[1]	2/2	100%

(1) Yvonne Greenstreet succeeded David L. Lacey as a non-executive director after he resigned from our Board of Directors per May 11, 2021. Until his resignation, David L. Lacey attended as a non-executive director two out of the two Board of Directors meetings with solely the non-executive directors being present held so far that year.

4.3.3 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 argenx's strategy, argenx's culture to ensure proper monitoring by the non-executive directors, the argenx' financial position as well as the results of its subsidiaries, acquisitions, large investment proposals, the yearly budget, director changes and the internal risk management and control system.

In 2021, specific attention was given to the statutory and governance topics such as the appointment of Ms. Yvonne Greenstreet as non-executive director as well as the re-appointment of Mr. Anthony Rosenberg, the impact of COVID-19 and related mitigating measures, business updates, review and approval of forecasts, the corporate dashboard and product portfolios, business & corporate development, review and approval of consolidated financial statements, update research & developments, updates to the remuneration policy, committee reports, financing of argenx, board rotation and succession process and plan, and the approval of the proposed agenda, explanatory notes and convocation notice for the (extraordinary) general meetings.

4.3.4 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 2021 this was performed by NASDAQ). The evaluation includes preparing specific questionnaires focusing on the relevant skills and competences most relevant for argenx, and the most material board topics and challenges facing argenx. The written questionnaire is then followed up by one-to-one interviews with each of the members 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 2021.

4.3.5 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 2021, the main points of discussion at the meetings were the key findings and risk areas of the 2021 gap analysis on compliance, the key findings of the 2021 gap analysis on ESG, the 2020 consolidated financial statements and press release, Deloitte's and PwC's 2020 audit reports, the interim consolidated financial statements and press releases, Deloitte's 2021 audit plan, the interim financial statements, review of quarterly forecasts, updates on internal control activities, updates on corporate audit activities, and updates on cash, cash equivalents and financial assets.

In 2021, six 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 2021 since appointment	Attendance %
Peter K. M. Verhaeghe	6/6	100%
Werner Lanthaler (chairperson)	6/6	100%
Anthony A. Rosenberg	6/6	100%
James M. Daly [1]	3/3	100%

(1) James M. Daly joined the audit and compliance committee in May 2021.

4.3.6 Report Remuneration and Nomination Committee

The remuneration and nomination committee assists the Board of Directors by, amongst other matters, regularly reviewing argenx's 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 2021, the main topics of discussion were the drafts of the new remuneration policy and the new equity incentive plan, the achievements of senior management's 2021 targets and pay-out of variable pay, the proposed 2021 equity incentive grants and the proposal to move to a single annual equity grant moment for recurring equity grants.

In 2021, two 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 2021 since appointment	Attendance %
Peter K. M. Verhaeghe	2/2	100%
Werner Lanthaler	2/2	100%
J. Donald deBethizy (chairperson)	2/2	100%
Yvonne Greenstreet	1/1	100%

4.3.7 Report Research and Development Committee

The research and development committee functions as a sounding board to argenx's research and development management, general management and the Board of Directors, and monitors the research and development goals, strategies and measures of argenx. In 2021, the committee held three formal meetings, in which it focused mainly on the vision and strategy on science at argenx.

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

Name	Number of meetings attended in 2021 since appointment	Attendance %
J. Donald deBethizy	3/3	100%
Pamela Klein	3/3	100%
David L. Lacey (chairperson)[1]	3/3	100%

(1) David L. Lacey resigned from our Board of Directors per May 11, 2021.

4.3.8 Report Commercial Committee

The commercial committee functions as a sounding board on branded and unbranded strategic marketing plans for the Board of Directors. In 2021, the committee held one formal meeting, in which it focused mainly on argenx's readiness in the U.S., Japan and EMEA in light of the envisaged launch of efgartigimod.

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

Name	Number of meetings attended in 2021 since appointment	Attendance %
Anthony A. Rosenberg	1/1	100%
James M. Daly (chairperson)	1/1	100%

4.4 Remuneration Report of the Remuneration and Nomination Committee

4.4.1 Remuneration Policy 2021 and Changes to the Policy

argenx's remuneration policy 2021 is available at argenx's website via https://www.argenx.com/sites/default/files/media-documents/argenx_remuneration_policy_final_approved_11_May_2021.pdf and is incorporated by reference into this URD. The remuneration policy was adopted by the General Meeting on May 11, 2021.

The aim is to achieve total remuneration packages that are attractive and in line with the market. argenx periodically reviews the positioning of the total remuneration of the senior management members compared to a reference group of peer companies active within the industries wherein argenx operates. Our remuneration policy and total compensation is positioned on the market median or slightly above the market median for fixed compensation, benefits and short term variable, with a strong emphasis on variable compensation. The long term variable is positioned between the 50th and the 75th percentile.

In order to realize the group's ambitions in this challenging environment, the organization needs to perform strongly and focus on the implementation of a sustainable strategy. Talented managers are indispensable in terms of achieving this goal. The remuneration policy aims to link this strategy and the Company's objectives to the performance and remuneration of management. In this way, the Group creates a globally consistent framework for the development, remuneration and empowerment of its people. The Group considers commitment, recognition and leadership as important foundations for employee engagement. This enables the Group to attract, retain and motivate the best talents to achieve both short-term and long-term objectives. This is all within the context of a globally consistent remuneration policy that rewards the contribution towards and the achievement of company objectives and the generation of shareholder value.

The reference group for our 2021 cash and equity remuneration benchmarking consisted of US and Europe based companies, taking into account our global ambitions as well as the primary markets for talent in which we compete. The companies in our reference group were selected based on a combination of characteristics which included their industry, years since initial public offer, number of employees, revenues, R&D expense, total level of cash & cash-equivalents, 30-day average market cap and 1-year and 3-year total return on stock. For 2021, the companies in our reference group were:

US companies	EU companies
ACADIA Pharmaceuticals	Abcam
Acceleron Pharma	ADC Therapeutics
Agios Pharmaceuticals	ALK-Abelló
Alnylam Pharmaceuticals	Ascendis Pharma
Amicus Therapeutics	BioNTech
Biohaven Pharmaceutical	Cosmo Pharmaceuticals
bluebird bio	CRISPR Therapeutics
Blueprint Medicines	Evotec
BridgeBio Pharma	Galapagos
CRISPR Therapeutics	Genmab
Denali Therapeutics	Idorsia
Fate Therapeutics	Mithra Pharmaceuticals
FibroGen	MorphoSys
Global Blood Therapeutics	Swedish Orphan Biovitrum
Intellia Therapeutics	uniQure
Mirati Therapeutics	Zealand Pharma
Reata Pharmaceuticals	
Sage Therapeutics	
Sarepta Therapeutics	
Xencor	

4.4.2 Remuneration of our Senior Management for 2021 and the Previous Years

The remuneration of our senior management (including our executive director, Mr. Tim Van Hauwermeiren) consists of the following fixed and variable components:

- fixed base compensation;
- short-term variable compensation;
- long-term variable compensation, in the form of stock options and restricted stock units;
- severance arrangements; and
- pension and fringe benefits.

Fixed base compensation
The base compensation of our senior management is determined on the basis of a benchmarking analysis completed by an independent consulting firm. The fixed cash compensation levels are set at or around the 50th percentile of U.S. and EU companies in our reference group for U.S. and EU based executives. The final determination of an executive director's fixed pay is made considering this 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.

Short-term variable compensation
The objective of our short-term annual incentive compensation is to ensure that our senior management team is incentivized to achieve performance targets in the shorter term. Variable cash incentives are granted for achieving predetermined specific performance targets. At the start of each financial year, the Board of Directors will determine our key priorities and will set specific, challenging performance targets in line with these priorities. The Board of Directors will determine the relative weight of each target and the metrics used for measuring their achievement. Our senior management team is eligible for an annual short-term variable incentive of their annual base compensation. The target percentage for this

purpose was set to 40% of the annual base compensation of a member of the senior management team, except for our executive director and our chief operating officer. The target variable cash incentive for our executive director shall be 60% of the fixed cash compensation if 100% of targets are achieved and 50% for our chief operating officer. In case of significant overachievement, the Board of Directors may decide to award higher variable pay to fairly reflect the individual's value contribution to argenx, but the variable pay will not exceed 120% of the fixed cash compensation.

Financial performance targets relate to building the business and typically make up 60% of the overall variable cash incentive targets and are aimed at significantly progressing our product candidates towards market approval and ultimately to the generation of sales and revenues to further enhance shareholder value and enable and support our further research and development activities. For further information on our financial performance targets, see in this section below und "Variable compensation determination – CEO".

Non-financial targets relate to building the organization and typically make up 40% of overall targets and are aimed at building and developing our organization into a sustainable, commercial stage, fully integrated global biopharmaceutical company in line with our identity and our core values.

Long-term incentive awards

Our Board of Directors intends to incentivize our senior management team by issuing stock options and/or restricted stock units from time to time to be able to attract and retain well-qualified senior management in connection with the Equity Incentive Plan, as set out below. Typically, stock options and restricted stock units are granted annually in accordance with our equity incentive grant allocation scheme which is regularly reviewed by our Board of Directors and particularly our remuneration and nomination committee.

Severance arrangements

We have entered into management contracts and employment agreements with our senior management team, each of which provides for certain minimum notice periods if their service or employment with us is terminated in certain circumstances as described below in section 6.11.2 "Related Party Transactions".

Pension and fringe benefits

Our senior management team participates in a defined contribution pension scheme operated by a third-party pension insurance organization. Our senior management team is entitled to customary fringe benefits, such as a company car and a hospitalization plan.

Performance of scenario analyses

In determining the remuneration package of each individual member of the senior management team, 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.

Relations between the remuneration of executives in comparison to other company personnel

The total company expense for the non-equity remuneration paid to our Chief Executive Officer (and only executive director) for the year ended December 31, 2021, equaled USD 1,238,772, representing 787% of the total company expense for the non-equity median compensation paid to our employees. This percentage was calculated on the basis of the last compensation payment period of the year ended December 31, 2021, over which the median non-equity remuneration of all argenx employees relative to their full time percentage was taken into account and set off against the non-equity remuneration of our executive director for the same period. We calculate the aforementioned percentage on the last compensation payment of the relevant period, because due to our rapid growth we deem it relevant to also include our latest hires in the comparison.

Please see below an overview of the annual change of compensation, of the performance of argenx and of the median remuneration on a full-time equivalent basis (annualized for employees who joined or left argenx during the year) of argenx's employees, other than the executive director, over the five most recent financial years:

	Financial year ended December 31,				
(In USD thousands, unless otherwise indicated)	2017	2018	2019	2020	2021
Non-equity remuneration of our CEO	648,108	926,577	952,995	1,094,367	1,238,772
Non-equity median salary paid to our employees	108,417	110,196	121,603	163,062	157,349
Ratio employee/CEO	16%	12%	13%	15%	13%
Average compensation paid to non-executive directors	60,249	59,891	60,372	57,925	54,484
Number of employees at end of year	73	105	188	336	650
Share price at end of year Euronext EUR	52.52	85.20	143.60	242.00	315.30
Share price at end of year Euronext USD	62.99	97.55	161.32	296.96	357.11

The decrease in the remuneration ratio between our key senior management and other employees between 2020 and 2021 is caused by the decreased median salary paid to our employees, also as a result of our expansion in the U.S. and Japan.

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 in this comparison, 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 evolvement 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 economic value.

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 Japan 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 persons), 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 average employee compared to the CEO for the financial year ended December 31, 2021
All employees	13%
European employees	8%
US employees	17%
Japan employees	9%

For the share based payments the ratios are as follows:

	Financial year ended December 31,				
	2017	2018	2019	2020	2021
Stock options granted to our CEO	80,000	80,000	80,000	50,000	25,000
Median stock options granted to our employees	2,500	2,500	2,800	2,900	981
Ratio employee/CEO	3.13%	3.13%	3.50%	5.80%	3.9%
Average number of stock options granted to non-executive directors	15,000	12,143	10,000	10,000	2,869
Median stock options granted to our employees	2,500	2,500	2,800	2,900	981
Ratio non-executive directors/employee	16.67%	20.59%	28.00%	29.00%	34.20%

The total employment costs (excluding any stock options) paid by us in the financial year 2021 was split between regions as follows:

	Total remuneration paid in the financial year ended December 31, 2021 (in USD millions)
EU	47.9
U.S.	64.8
Japan	7.9

As a result of linking long term targets, designed to increase argenx's performance in the present as well as the future, the variable compensation of our senior management team intends to align the interests of the senior management team to that of the (other) stakeholders of argenx. The Board of Directors believes that a remuneration package comprised of a fixed compensation a variable compensation linked to individual targets as well as options linked to a vesting scheme is most suitable to achieve this goal.

Remuneration and Benefits of the CEO

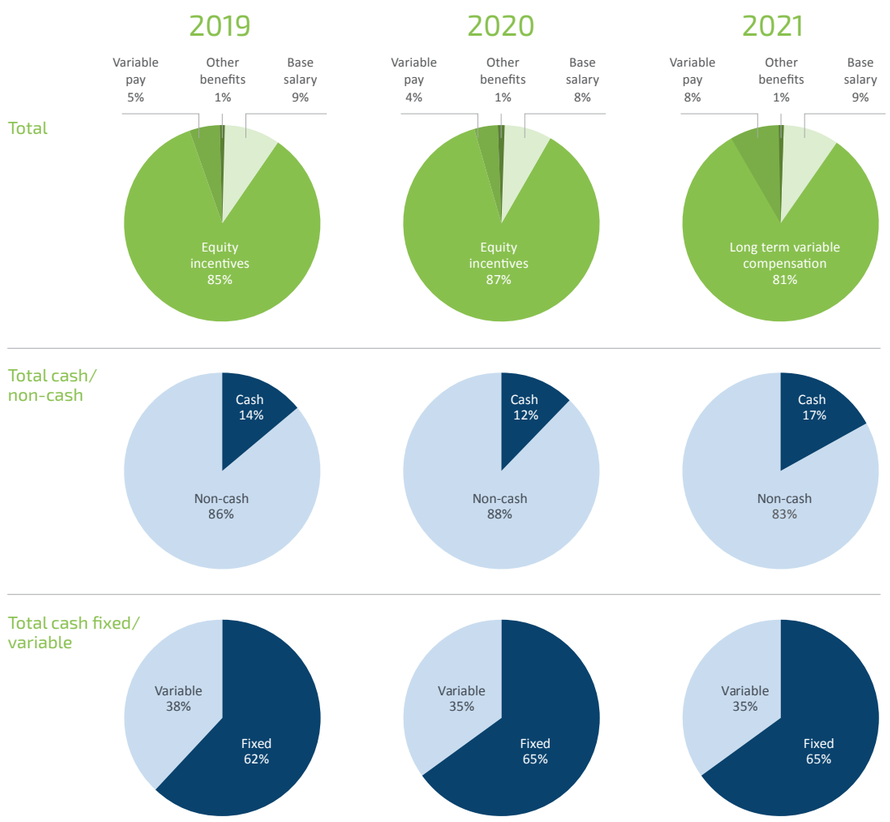
The following table sets forth information regarding compensation paid by us for Tim Van Hauwermeiren during the year ended December 31, 2021.

Compensation in USD	Financial year ended December 31,
Fixed base compensation	651,986
Long-term variable compensation, in the form of stock options [1]	3,895,370
Long-term variable compensation, in the form of restricted stock units	2,084,509
Employer social security contribution stock options [2]	–
Non-equity incentive plan compensation	586,787
Pension contributions	26,894
Social security costs	3,456
Other [3]	14,827
Total	**7,263,828**

(1) Amount shown represents the expenses with respect to the stock option awards granted in 2021 to Mr. Van Hauwermeiren measured using the Black Scholes formula. For a description of the assumptions used in valuing these awards, see note 14 "Share-based payments" to our consolidated financial statements in chapter 7 "Consolidated Financial Statements – audited as of and for the years ended December 31, 2021, 2020 and 2019". These amounts do not reflect the actual economic value realized by Mr. Van Hauwermeiren.
(2) argenx 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, argenx makes a calculation of the exposure.
(3) Consists of USD 14,626 attributable to the lease of a company car and USD 201 in employer-paid medical insurance premiums.

Variable compensation determination – CEO

The mix between fixed and variable remuneration components for our executive director for at least the last three years is set out below.



For 2021, the variable pay targets for our senior management included targets relating to the following topics (in addition to a number of non-disclosed targets)

1. Building the business:
   a. Research progress: Nominated new indications for specified product candidates;
   b. Commercial development: Established launch key performance indicators;
   c. Regulatory approvals: Obtained regulatory approval key performance indicators relating to VYVGART in the U.S. and Japan;
   d. Cash management and financing: Raised a minimum amount of capital to support the business objectives;
   e. Supply chain capabilities: Built out our global supply chain in preparation of the commercial launch and clinical development objectives of VYVGART.

2. Building the organization:
   a. Team development: Accomplished the recruitment objectives for commercial positions as well as the recruitment and onboarding of a number of key senior leadership roles;
   b. Legal / compliance development: Put in place a number of policies, processes, resources and training to prepare the company for its commercial life;
   c. Company culture focus: Delivered on our goals inclusive of imbedding and reinforcing our cultural values and leading by example.

All of the targets for 2021 were achieved, with overperformance of up to 200% granted for some targets, particularly where the targets were overachieved in absolute terms, or where the targets were achieved despite significant unforeseen obstacles, including relating to COVID-19.

Our CEO's variable pay targets related to:

Building the business (60%):
- If accelerated approval, deliver on number of new patient starts, if December approval, research progress target (40%)
- Commercial development and launch preparedness targets (20%)

Building the organization (40%):
- Team development (20%)
- Company culture (20%)

Our Board of Directors resolved that each of the variable pay targets of our CEO had been met in 2021, and that an overperformance warranted 150% pay-out of the variable pay, considering among other things the successful overcoming of significant challenges coming out of the COVID-19 pandemic in this pre-launch year and taking into account the success in recruiting and onboarding key functions in the senior management team.

The ratio between fixed and variable payments to our CEO for the financial year ended December 31, 2021 equals USD 651,986/USD 586,787 or 52.6%/47.4%.

Remuneration of Other Members of the Senior Management

The following table sets forth information regarding aggregate compensation paid by us for the members of our executive management (excluding our CEO Tim Van Hauwermeiren) during the year ended December 31, 2021. We note that these numbers also include compensation paid to persons who have been part of our executive management for part of 2021 (being Karl Gubitz).

Compensation in USD	Financial year ended December 31,
Fixed base compensation	2,812,668
Long-term variable compensation, in the form of stock options [1]	11,165,679
Long-term variable compensation, in the form of restricted stock units	5,940,183
Employer social security contribution stock options[2]	4,171,822
Non-equity incentive plan compensation	1,433,378
Termination benefits	381,522
Pension contributions	123,002
Social security costs	785,489
Other[3]	258,950
Total	**27,072,693**

(1) Amount shown represents the expenses with respect to the stock option awards granted in 2021 to Mr. Keith Woods, Mr. Karl Gubitz, Prof. Hans de Haard, Mr. Wim Parys, Mr. Arjen Lemmen and Miss Andria Wilk measured using the Black Scholes formula. For a description of the assumptions used in the valuing these awards, see note 14 "Share-based payments" to our consolidated financial statements in chapter 7 "Consolidated Financial Statements – audited as of and for the years ended December 31, 2021, 2020 and 2019". These amounts do not reflect the actual economic value realized by these members of our senior management.
(2) argenx 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, argenx makes a calculation of the exposure.
(3) Consists of USD 78,181 attributable to the leases of company cars, USD 136,893 in car, housing and other allowances and USD 43,876 in employer-paid medical insurance premiums.

Option Awards for Our Senior Management

The following table sets forth information regarding option awards granted to our senior management during the year ended December 31, 2021:

Name	Stock options	Expiration date	Exercise price (IN USD)
Tim Van Hauwermeiren [1]	25,000	December 24, 2031	350.20
Eric Castaldi [2]	–	–	–
Keith Woods	16,000	December 24, 2031	350.20
Karl Gubitz [2]	24,000	July 1, 2031	288.93
Hans de Haard [1]	16,000	December 24, 2031	350.20
Dirk Beeusaert [3]	–	–	–
Wim Parys [4]	–	–	–
Arjen Lemmen [1]	16,000	December 24, 2031	350.20
Andria Wilk [1]	4,446	December 24, 2031	350.20

(1) On December 24, 2021, the Company has granted options for which each beneficiary has a 60 day period to choose between a contractual term of five or ten years.
(2) Eric Castaldi resigned from his position as chief financial officer on our senior management in June 2021 and was succeeded by Karl Gubitz.
(3) Mr. Beeusaert has retired per December 31, 2021 and, therefore, was not granted any equity incentives in 2021.
(4) Mr. Parys will retire with effect from March 30, 2022 and, therefore, was not granted any equity incentives in 2021.

The following table sets forth information regarding restricted stock units granted to our senior management during the year ended December 31, 2021:

Name	Restricted stock units	Expiry date
Tim Van Hauwermeiren	5.700	December 24, 2031
Eric Castaldi [1]	–	–
Keith Woods	3.600	December 24, 2031
Karl Gubitz [1]	5.400	July 1, 2025
Hans de Haard	3.600	December 24, 2031
Dirk Beeusaert [2]	–	–
Wim Parys [3]	–	–
Arjen Lemmen	3.600	December 24, 2031
Andria Wilk	988	24/12/2031

(1) Eric Castaldi resigned from his position as chief financial officer on our senior management in June 2021 and was succeeded by Karl Gubitz.
(2) Mr. Beeusaert has retired per December 31, 2021 and, therefore, was not granted any equity incentives in 2021.
(3) Mr. Parys will retire with effect from March 30, 2022 and, therefore, was not granted any equity incentives in 2021.

Following our annual remuneration and benchmarking exercise the base amount of equity for the CEO was adjusted downward (from the approved remuneration policy 2021) to 32,000 stock options and 7,200 restricted stock units. The Remuneration and Nomination Committee discussed a recommendation of 130% of this base amount based on performance (being 41,600 stock options and 9.360 restricted stock units). However, following consultation of the CEO in line with best practice principle 3.2.2. of the Dutch Corporate Governance Code, at the request of the CEO, the Board of Directors agreed to grant only 25,000 stock options and 5,700 restricted stock units to the CEO and to recommend placing the difference (being 16,600 stock options and 3,660 restricted stock units) at the disposition of the CEO for distribution to key individuals in the April 1, 2022 equity grant.

The table below shows the stock options held at January 1, 2021 and the stock options granted to our senior management which have vested during the year ended December 31, 2021, as well as the stock options scheduled to vest in the years ending December 31, 2022, December 31, 2023 and December 31, 2024 (in number of stock options), and the respective exercise price of such stock options:

Name	Total stock options held on January, 1, 2021	Stock options granted in 2021	Stock options forfeited in 2021	Stock options exercised in 2021	Total stock options held on December 31, 2021		Exercise price (in USD)	Stock options vested through 2020	Stock options vested through 2021	Stock options to vest in 2022	Stock options to vest in 2023	Stock options to vest in 2024
Tim Van Hauwermeiren	290,000	25,000	–	–	315,000		23.98	80,000				
							97.77	53,333	26,667			
							153.75	26,667	26,666	26,667		
							280.43		16,667	16,666	16,667	
							350.20			8,333	8,334	8,333
Total	**290,000**	**25,000**	–	–	**315,000**			**160,000**	**70,000**	**51,666**	**25,001**	**8,333**
Eric Castaldi[1]	171,400	–	–	(46,400)	125,000		23.98	25,000				
							97.77	50,000				
							153.75	50,000				
Total	**171,400**	–	–	**(46,400)**	**125,000**			**125,000**	–	–	–	–
Keith Woods	155,000	16,000	–	(30,000)	141,000		97.77	8,333	16,667			
							153.75	16,667	16,666	16,667		
							280.43		16,667	16,666	16,667	
							350.20			5,333	5,334	5,333
Total	**155,000**	**16,000**	–	**(30,000)**	**141,000**			**25,000**	**50,000**	**38,666**	**22,001**	**5,333**
Karl Gubitz [1]	–	24,000	–	–	24,000		288.93			11,333	8,000	4,667
Total	–	**24,000**	–	–	**24,000**			–	–	**11,333**	**8,000**	**4,667**
Hans de Haard	545,975	16,000	–	–	561,975		2.76	144,822				
							8.12	109,000				
							10.72	28,200				
							12.99	28,200				
							16.01	28,200				
							20.85	14,353				
							23.98	43,200				
							97.77	33,333	16,667			
							153.75	16,666	16,668	16,666		
							280.43		16,667	16,666	16,667	
							350.20			5,333	5,334	5,333
Total	**545,975**	**16,000**	–	–	**561,975**			**445,974**	**50,002**	**38,665**	**22,001**	**5,333**

(1) Eric Castaldi resigned from his position as chief financial officer on our senior management in June 2021 and was succeeded by Karl Gubitz.

Name	Total stock options held on January, 1, 2021	Stock options granted in 2021	Stock options forfeited in 2021	Stock options exercised in 2021	Total stock options held on December 31, 2021		Exercise price (in USD)	Stock options vested through 2020	Stock options vested through 2021	Stock options to vest in 2022	Stock options to vest in 2023	Stock options to vest in 2024
Dirk Beeusaert [2]	204,682	–	–	(54,682)	150,000		91.54	23,500	4,700			
							97.77	14,533	7,267			
							128.53	30,757	19,243			
							222.16	12,756	37,244			
Total	**204,682**	–	–	**(54,682)**	**150,000**			**81,546**	**68,454**	–	–	–
Wim Parys	225,000	–	–	–	225,000		97.77	83,333	41,667			
							153.75	16,667	16,666	16,667		
							280.43		16,667	16,666	16,667	
Total	**225,000**	–	–	–	**225,000**			**100,000**	**75,000**	**33,333**	**16,667**	–
Arjen Lemmen	136,211	16,000	–	(6,430)	145,781		20.85	4,306				
							23.98	6,328				
							91.54	2,361	834			
							97.77	8,452	7,500			
							153.75	24,963	12,519	12,518		
							280.43		16,667	16,666	16,667	
							350.20			5,333	5,334	5,333
Total	**136,211**	**16,000**	–	**(6,430)**	**145,781**			46,410	37,520	34,517	22,001	5,333
Andria Wilk	19,300	4,446			23,746		153.75	4,693	2,353	2,354		
							280.43		4,575	2,663	2,662	
							350.20			1,482	1,482	1,482
Total	**19,300**	**4,446**			**23,746**			4,693	6,928	6,499	4,144	1,482

(1) Eric Castaldi resigned from his position as chief financial officer on our senior management in June 2021 and was succeeded by Karl Gubitz.
(2) Dirk Beeusaert retired effective December 31, 2021 and was succeeded by Malini Moorthy effective February 14, 2022.

The table below shows the restricted stock units held at January 1, 2021 and the restricted stock units granted to our senior management which have vested during the year ended December 31, 2021, as well as the restricted stock units scheduled to vest in the years ending December 31, 2022, December 31, 2023, December 31, 2024 and December 31, 2025 (in number of restricted stock units):

Name	Total restricted stock units held on January, 1, 2021	Restricted stock units granted in 2021	Restricted stock units forfeited in 2021	Restricted stock units exercised in 2021		Total restricted stock units held on December 31, 2021	Restricted stock units vested through 2021	Restricted stock units to vest in 2022	Restricted stock units to vest in 2023	Restricted stock units to vest in 2024	Restricted stock units to vest in 2025
Tim Van Hauwermeiren	–	5,700	–	–		5,700	–	1,425	1,425	1,425	1,425
Total	–	5,700	–	–		**5,700**	–	**1,425**	**1,425**	**1,425**	**1,425**
Eric Castaldi [1]	–	–	–	–		–	–	–	–	–	–
Total	–	–	–	–		–	–	–	–	–	–
Keith Woods	–	3,600	–	–		3,600	–	900	900	900	900
Total	–	3,600	–	–		**3,600**	–	**900**	**900**	**900**	**900**
Karl Gubitz [1]	–	5,400	–	–		5,400	–	1,350	1,350	1,350	1,350
Total	–	5,400	–	–		**5,400**	–	1,350	1,350	1,350	1,350
Hans de Haard	–	3,600	–	–		3,600	–	900	900	900	900
Total	–	3,600	–	–		**3,600**	–	**900**	**900**	**900**	**900**
Dirk Beeusaert	–	–	–	–		–	–	–	–	–	–
Total	–	–	–	–		–	–	–	–	–	–
Wim Parys	–	–	–	–		–	–	–	–	–	–
Total	–	–	–	–		–	–	–	–	–	–
Arjen Lemmen	–	3,600	–	–		3,600	–	900	900	900	900
Total	–	3,600	–	–		**3,600**	–	**900**	**900**	**900**	**900**
Andria Wilk	–	988	–	–		988	–	247	247	247	
Total	–	988	–	–		**988**	–	247	247	247	

(1) Eric Castaldi resigned from his position as chief financial officer on our senior management in June 2021 and was succeeded by Karl Gubitz.
(2) Dirk Beeusaert retired effective December 31, 2021 and was succeeded by Malini Moorthy effective February 14, 2022.

The table below shows the remaining term of the stock options and restricted stock units held by our senior management during the year ended December 31, 2021.

Name	Number of Stock options	Remaining term on December 31, 2021 (rounded up)	Number of restricted stock units[4]
Tim Van Hauwermeiren [1]	80,000	6 years	5,700
	80,000	7 years	
	80,000	8 years	
	50,000	9 years	
	25,000	5 years / 10 years[1]	
Eric Castaldi [2]	17,360	2 years	
	18,120	3 years	
	25,000	6 years	
	32,640	7 years	
	31,880	8 years	
Keith Woods	25,000	7 years	3,600
	50,000	8 years	
	50,000	9 years	
	16,000	10 years	
Karl Gubitz [2]	24,000	10 years	5,400
Hans De Haard [1]	108,996	0.5 years	3,600
	35,826	3 years	
	109,000	3 years	
	28,200	4 years	
	28,200	4.5 years	
	28,200	5 years	
	14,353	5.5 years	
	43,200	6 years	
	50,000	7 years	
	50,000	8 years	
	50,000	9 years	
	16,000	5 years / 10 years[1]	
Dirk Beeusaert [3]	28,200	1.5 years	–
	21,800	2 years	
	50,000	2.5 years	
	50,000	3.5 years	
Wim Parys	125,000	2 years	–
	50,000	4 years	
	50,000	8 years	
Arjen Lemmen [1]	2,500	1.5 years	3,600
	50,000	3 years	
	4,306	5.5 years	
	6,328	6 years	
	695	6.5 years	
	15,952	7 years	
	50,000	9 years	
	16,000	5 years / 10 years[1]	
Andria Wilk [1]	9,400	3 years	988
	9,900	4 years	
	4,446	5 years / 10 years[1]	

(1) On December 24, 2021, argenx granted options for which the beneficiary has a 60 day period to choose between a contractual term of five or ten years.
(2) Eric Castaldi resigned from his position as chief financial officer on our senior management in June 2021 and was succeeded by Karl Gubitz.
(3) Dirk Beeusaert retired effective December 31, 2021 and was succeeded by Malini Moorthy effective February 14, 2022.
(4) In accordance with the equity plan, restricted stock units, once vested, will be settled against the issuance of ordinary shares in argenx SE. Such shares have no expiry date and may be held by the participant without limitation.

The table below shows the stock options exercised by our senior management during the year ended December 31, 2021 and the exercise price of those stock options. Per exercised option, one share was issued.

Name	Number of Stock options	Exercise price (in USD)
Tim Van Hauwermeiren	–	–
Eric Castaldi [1]	28,200	16.01
	18,200	23.98
Keith Woods	5,000	23.98
	25,000	97.77
Karl Gubitz [1]	–	–
Hans de Haard	–	–
Dirk Beeusaert [2]	39,682	20.85
	15,000	23.98
Wim Parys	–	–
Arjen Lemmen	3,215	12.99
Arjen Lemmen	3,215	16.01
Andria Wilk	–	–
Total	**137,512**	

(1) Eric Castaldi resigned from his position as chief financial officer on our senior management in June 2021 and was succeeded by Karl Gubitz.
(2) Dirk Beeusaert retired effective December 31, 2021 and was succeeded by Malini Moorthy effective February 14, 2022.

4.4.3 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 the remuneration and nomination committee, within the limits of the remuneration policy adopted by the shareholders at the General Meeting. The description below reflects the remuneration policy approved by our General Meeting held on May 11, 2021.

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 or, 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 restricted stock units.

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 denominated in USD	Fees denominated in EUR
Board of Directors	Chairperson	76,878	65,000
	Member	41,396	35,000
Audit & Complance committee/R&D	Chairperson	17,741	15,000
	Member	8,871	7,500
Remuneration & Nomination committee/ Commercial committee	Chairperson	11,827	10,000
	Member	5,913	5,000

Long-term incentive plan

The Board of Directors intends to incentivize the non-executive directors by issuing stock options and/or restricted stock units from time to time to be able to attract and retain well-qualified non-executive directors in connection with the Equity Incentive Plan. The Board of Directors grants stock options and restricted stock units to the non-executive directors on the recommendation of the remuneration and nomination committee. Such stock option and restricted stock unit grants are based on an equity incentive grant allocation scheme established by the Board of Directors pursuant to the Option Plan. The conditions of our Equity Incentive Plan apply to our non-executive directors, as set forth in section 4.4.4 “Long-Term Incentives Granted to Key Persons – Equity Incentive Plan”.

Success payment

In exceptional circumstances, the Board of Directors may decide to reward a non-executive director with a success payment relating to the occurrence of specific events achieved through the exceptional efforts of that person (such as a platform licensing or product licensing deal brokered by that non-executive director). To date, no such success payments have been made or promised by us to our non-executive directors.

Pursuant to the remuneration policy, in case of a dismissal, non-executive directors will not be entitled to a severance payment.

The following table sets forth the information regarding the compensation earned by our non-executive directors during the year ended December 31, 2021:

Name (in USD)	Fees earned or paid in cash	Stock option awards[1]	Restricted stock units awards[2]	Total
Peter Verhaeghe	91,662	392,743	210,120	694,526
David L. Lacey[3]	19,712	392,743	210,120	622,576
Werner Lanthaler	65,051	392,743	210,120	667,914
J. Donald deBethizy	62,094	392,743	210,120	664,957
Pamela Klein	50,266	392,743	210,120	653,130
A. A. Rosenberg	56,180	392,743	210,120	659,044
James M. Daly	59,137	392,743	210,120	662,000
Yvonne Greenstreet[3]	30,459	514,154	260,034	804,647

(1) These amounts do not reflect the actual economic value realized by the non-executive director. Amount shown represents the expenses with respect to the stock option awards granted in 2021 to the non-executive directors measured using the Black Scholes formula. For a description of the assumptions used in valuing these awards, see note 14 “Share-based payments” to our consolidated financial statements in chapter 7 “Consolidated Financial Statements – audited as of and for the years ended December 31, 2021, 2020 and 2019”.

(2) These amounts do not reflect the actual economic value realized by the non-executive director. Amount shown represents the expenses with respect to the restricted stock unit awards granted in 2021 to the non-executive directors measured using the Black Scholes formula. For a description of the assumptions used in valuing these awards, see note 14 “Share-based payments” to our consolidated financial statements in chapter 7 “Consolidated Financial Statements – audited as of and for the years ended December 31, 2021, 2020 and 2019”.

(3) David L. Lacey resigned from our Board of Directors per May 11, 2021 and was succeeded by Yvonne Greenstreet. On March 3, 2022, Yvonne Greenstreet stepped down from her position as member of our Board of Directors.

Together
We Discover

Daniel

How He Found Ways to Balance Mental and Physical Health with MG*

Growing up, Daniel was always involved in sports and fitness, and he eventually established a career in the field. When he was diagnosed with myasthenia gravis (MG), his world was turned upside down.

Patient Story

**Paid contributor to MG United.*

How did you react when you received your myasthenia gravis diagnosis?

I didn't really know much about MG, so I didn't really know what to think. The only thing I knew about MG was information I gained through my then-girlfriend. Her dad has MG. Ironically, she had mentioned MG when she was taking me to appointments. He was the only person I knew living with MG, and he seemed to be living a pretty normal life.

What has changed about your life since your myasthenia gravis diagnosis, and what has stayed the same?

For the most part, my life is still pretty normal. Some things stayed the same, like I'm working full time and working out five or six times a week, although I had to slowly build back up to using heavier weights. I have to be careful about not pushing myself too hard, and I worked with my doctor to figure out what exercises were right for me. I know not everyone with MG can do as much as I have been able to do.

But some things certainly did change. I had to start cutting back on social outings. My friends noticed, but when I explained it to them, they were understanding. And I need more sleep than I did before. For me, it's really been about finding the right balance of what I want to do and what I need to do to take care of my body.

What challenges did you face while continuing to work? Did you have to set new expectations or modify your workload or schedule?

I'm very lucky to have the job that I do because I was able to modify my schedule. I worked with my manager when my symptoms were really bad. I would go in when I could. My manager and coworkers knew that I would do all that I could, so they were understanding when I needed to come in late or miss a day. When I had a myasthenia gravis–related surgery, I took some time off to recover and find my new balance. When I was ready to come back, my position was waiting for me.

The table below shows the stock options held at January 1, 2021 and the stock options granted to the non-executive directors which have vested during the year ended December 31, 2021, as well as the stock options scheduled to vest in the years ending December 31, 2022, December 31, 2023 and December 31, 2024 (in number of stock options), and the respective exercise price of such stock options:

Name	Total stock options held on January, 1, 2021	Stock options granted in 2021	Stock options exercised in 2021	Total stock options held on December 31, 2021		Exercise price (in USD)	Stock options vested through 2020	Stock options vested through 2021	Stock options to vest in 2022	Stock options to vest in 2023	Stock options to vest in 2024
Peter Verhaeghe	58,595	2,700	–	61,295		2.76	11,626				
						4.47	1,969				
						8.12	5,000				
						12.89	10,000				
						97.77	6,667	3,333			
						153.75	3,333	3,334	3,333		
						280.43		3,333	3,334	3,333	
						350.20					2,700
Total	**58,595**	**2,700**	**–**	**61,295**			**38,595**	**10,000**	**6,667**	**3,333**	**2,700**
David L. Lacey [1]	67,800	2,700	(5,000)	65,500		8.12	7,800				
						12.89	10,000				
						23.98	15,000				
						97.77	6,667	3,333			
						153.75	3,333	3,334	3,333		
						280.43		3,333	3,334	3,333	
						350.20					2,700
Total	**67,800**	**2,700**	**(5,000)**	**65,500**			**42,800**	**10,000**	**6,667**	**3,333**	**2,700**
Werner Lanthaler	30,000	2,700	(4,420)	28,280		97.77	6,667	3,333			
						153.75	2,247	3,333			
						280.43		3,333	3,334	3,333	
						350.20					2,700
Total	**30,000**	**2,700**	**(4,420)**	**28,280**			**8,914**	**9,999**	**3,334**	**3,333**	**2,700**
J. Donald deBethizy	47,500	2,700	(7,500)	42,700		12.89	10,000				
						97.77	6,667	3,333			
						153.75	3,333	3,334	3,333		
						280.43		3,333	3,334	3,333	
						350.20					2,700
Total	**47,500**	**2,700**	**(7,500)**	**42,700**			**20,000**	**10,000**	**6,667**	**3,333**	**2,700**

Name	Total stock options held on January, 1, 2021	Stock options granted in 2021	Stock options exercised in 2021	Total stock options held on December 31, 2021		Exercise price (in USD)	Stock options vested through 2020	Stock options vested through 2021	Stock options to vest in 2022	Stock options to vest in 2023	Stock options to vest in 2024
Pamela Klein	50,000	2,700	(7,500)	45,200		12.96	2,500				
						12.89	10,000				
						97.77	6,667	3,333			
						153.75	3,333	3,334	3,333		
						280.43		3,333	3,334	3,333	
						350.20					2,700
Total	**50,000**	**2,700**	**(7,500)**	**45,200**			**22,500**	**10,000**	**6,667**	**3,333**	**2,700**
A. A. Rosenberg	45,000	2,700	**(1,160)**	46,540		16.00	15,000				
						97.77	6,667	3,333			
						153.75	2,173	3,334	3,333		
						280.43		3,333	3,334	3,333	
						350.20					2,700
Total	**45,000**	**2,700**	**(1,160)**	**46,540**			**23,840**	**10,000**	**6,667**	**3,333**	**2,700**
James M. Daly	35,000	2,700	–	37,700		90.97	2,500	2,500			
						97.77	6,667	3,333			
						153.75	3,333	3,334	3,333		
						280.43		3,333	3,334	3,333	
						350.20					2,700
Total	**35,000**	**2,700**	**–**	**37,700**			**12,500**	**12,500**	**6,667**	**3,333**	**2,700**
Yvonne Greenstreet [1]	–	4,050	–	4,050		288.93			1350	1350	1350
Total	**–**	**4,050**	**–**	**4,050**			**–**	**–**	**1,350**	**1,350**	**1,350**

(1) David L. Lacey resigned from our Board of Directors per May 11, 2021 and was succeeded by Yvonne Greenstreet. On March 3, 2022, Yvonne Greenstreet stepped down from her position as member of our Board of Directors.

The table below shows the restricted stock units held at January 1, 2021 and the restricted stock units granted to the non-executive directors which have vested during the year ended December 31, 2021, as well as the restricted stock units scheduled to vest in the years ending December 31, 2022, December 31, 2023, December 31, 2024 and December 31, 2025 (in number of restricted stock units):

Name	Total restricted stock units held on January, 1, 2021	Restricted stock units granted in 2021	Restricted stock units forfeited in 2021	Restricted stock units exercised in 2021		Total restricted stock units held on December 31, 2021	Restricted stock units vested through 2021	Restricted stock units to vest in 2022	Restricted stock units to vest in 2023	Restricted stock units to vest in 2024	Restricted stock units to vest in 2025
Peter Verhaeghe	–	600	–	–		600	–	150	150	150	150
Total	–	600	–	–		600	–	**150**	**150**	**150**	**150**
David L. Lacey [1]	–	600	–	–		600	–	150	150	150	150
Total	–	600	–	–		600	–	**150**	**150**	**150**	**150**
Werner Lanthaler	–	600	–	–		600	–	150	150	150	150
Total	–	600	–	–		600	–	**150**	**150**	**150**	**150**
J. Donald deBethizy	–	600	–	–		600	–	150	150	150	150
Total	–	600	–	–		600	–	**150**	**150**	**150**	**150**
Pamela Klein	–	600	–	–		600	–	150	150	150	150
Total	–	600	–	–		600	–	**150**	**150**	**150**	**150**
A. A. Rosenberg	–	**600**	–	–		**600**	–	150	150	150	150
Total	–	**600**	–	–		**600**	–	**150**	**150**	**150**	**150**
James M. Daly	–	**600**	–	–		**600**	–	150	150	150	150
Total	–	**600**	–	–		**600**	–	**150**	**150**	**150**	**150**
Yvonne Greenstreet [1]	–	900	–	–		900	–	225	225	225	225
Total	–	**900**	–	–		**900**	–	**225**	**225**	**225**	**225**

(1) David L. Lacey resigned from our Board of Directors per May 11, 2021 and was succeeded by Yvonne Greenstreet. On March 3, 2022, Yvonne Greenstreet stepped down from her position as member of our Board of Directors.

The table below shows the remaining term of the stock options and restricted stock units held by the non-executive directors during the year ended December 31, 2021.

Name	Number of Stock options	Remaining term on December 31, 2021 (rounded up)	Number of restricted stock units[2]
Peter Verhaeghe	8,741	0.5 years	600
	4,854	3 years	
	5,000	3 years	
	10,000	4.5 years	
	10,000	7 years	
	10,000	8 years	
	10,000	9 years	
	2,700	10 years	
David L. Lacey [1]	7,800	3 years	600
	10,000	4.5 years	
	15,000	6 years	
	10,000	7 years	
	10,000	8 years	
	10,000	9 years	
	2,700	10 years	
Werner Lanthaler	10,000	2 years	600
	5,580	8 years	
	10,000	9 years	
	2,700	10 years	
J. Donald deBethizy	10,000	4.5 years	600
	10,000	7 years	
	10,000	8 years	
	10,000	9 years	
	2,700	10 years	
Pamela Klein	2,500	3.5 years	600
	10,000	4.5 years	
	10,000	7 years	
	10,000	8 years	
	10,000	9 years	
	2,700	10 years	
A. A. Rosenberg	15,000	5 years	600
	10,000	7 years	
	8,840	8 years	
	10,000	9 years	
	2,700	10 years	
James M. Daly	5,000	6.5 years	600
	10,000	7 years	
	10,000	8 years	
	10,000	9 years	
	2,700	10 years	
Yvonne Greenstreet	4,050	10 years	900

(1) David L. Lacey resigned from our Board of Directors per May 11, 2021 and was succeeded by Yvonne Greenstreet. On March 3, 2022, Yvonne Greenstreet stepped down from her position as member of our Board of Directors.
(2) In accordance with the equity plan, restricted stock units, once vested, will be settled against the issuance of ordinary shares in argenx SE. Such shares have no expiry date and may be held by the participant without limitation

The table below shows the stock options exercised by our non-executive directors during the year ended December 31, 2021 and the exercise price of those stock options. Per exercised option, one share was issued.

Name	Number of Stock options	Exercise price (in USD)
Peter Verhaeghe	–	–
David L. Lacey [1]	5,000	8.12
Werner Lanthaler	4,420	153.75
J. Donald deBethizy	7,500	12.96
Pamela Klein	7,500	12.96
A. A. Rosenberg	1,160	153.75
James M. Daly	–	–
Yvonne Greenstreet [1]	–	–
Total	**25,580**	

(1) David L. Lacey resigned from our Board of Directors per May 11, 2021 and was succeeded by Yvonne Greenstreet. On March 3, 2022, Yvonne Greenstreet stepped down from her position as member of our Board of Directors.

4.4.4 Long-Term Incentives Granted to Key Persons – Equity Incentive Plan

Our current equity incentive plan providing for the granting of a mix of stock options and restricted stock units was approved by our Board of Directors on March 15, 2021 and subsequently amended on December 15, 2021 (the **Equity Incentive Plan**). The aim of the 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 the growth and performance of argenx, to increase their incentive to contribute to our value and to attract and retain individuals who are key to argenx.

In connection with the Equity Incentive Plan, our Board of Directors has also established an equity incentive allocation scheme. The equity incentive allocation scheme contains (i) the date on which stock options and restricted stock units are granted each year, which shall be the same date each year and (ii) the number of stock options and restricted stock units granted to each person or to each group of persons, which shall be based on objective criteria only. Starting January 1, 2023, the regular annual grant of equity incentives to existing employees will be once a year in July for all participants of the Equity Incentive Plan.

Our Board of Directors, in each case subject to the approval of the majority of the non-executive directors, may grant stock options and restricted stock units to our senior management, directors, all other key employees, or key outside

consultants or advisors and in accordance with the equity incentive allocation scheme. Our Board of Directors may also grant stock options and restricted stock units at its discretion outside of the equity incentive allocation scheme, but only in a period when no inside information (as specified in our insider trading policy) is available. Persons to whom equity incentives are granted cannot refuse to accept such equity incentives.

The aggregate number of shares that may be available for the issuance of stock options and restricted stock units is based between the 50th and the 75th percentile of our reference group.

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 option fully vesting upon the third anniversary of the date of grant, subject, in each case, to the optionee's continued status. 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 (at the election of the optionee) 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.

Restricted stock units granted under the Equity Incentive Plan shall vest over a period of four years with repect to one fourth of the shares upon each anniversary of the date of grant. At the time of vesting, the holder of such restricted stock unit receives argenx shares for free in the number equal to the number of restricted stock units vested minus a certain number of shares required to cover employee taxes payable by argenx on behalf of the holder of restricted stock units, if applicable.

In the case 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 argenx's assets or (iii) dissolution and/or liquidation of argenx, then 100% of any unvested equity incentives shall vest.

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 restricted stock units, provided that we will compensate any affected optionee for any direct negative impact of such amendment.

4.5 Risk Appetite & Control

As a Dutch comefore 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. THE RISK MITIGATION ACTIONS AND RISK MANAGEMENT DESCRIBED IN THIS SECTION HAVE BEEN FULLY TAKEN INTO ACCOUNT BY US WHEN 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.

4.5.1 Introduction

This Universal Registration Document, in application of article 9 sub 12 of the Prospectus Regulation contains (whether in the body of the document or in the documents incorporated by reference) the information required for us to be disclosed in our annual financial reporting and as such also serves as our annual report for the financial year 2021.

Under Dutch law, we are required to include in our annual report 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.

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 maintain profitability. All but one of our product candidates are either in preclinical, early-stage clinical or clinical development or market approval has been requested for them, but has not (yet) been granted, and only VYVGART™ for the treatment of gMG has obtained regulatory approval in the U.S. and in Japan. Our trials may fail and even if they succeed we may be unable to commercialize any or all of our product candidates due to a lack of, or delay in, regulatory approval or for other reasons.	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 create novel, differentiated product candidates from our proprietary technology platforms which regularly feed our product candidate pipeline.
We will face significant challenges in successfully commercializing our products.	We plan to focus on the development and commercialization of the product candidates that we believe have a clear clinical and regulatory approval pathway and that we believe we can commercialize successfully, when and if approved. Our commercialization strategy for any product candidates that are approved will focus on key academic centers, specialist physicians and advocacy groups, as well as on providing patients with support programs and maximizing product access and reimbursement. We plan to partner product candidates that we believe have promising utility in disease areas or patient populations that are better served by the resources of larger biopharmaceutical companies.
Nearly all aspects of our activities are subject to substantial regulation. No assurance can be given that any of our product candidates will fulfill regulatory compliance. Failure to comply with such regulations could result in delays, suspension, refusals and withdrawal of approvals, as well as fines.	We are establishing a robust quality management system to ensure compliance with current good laboratory practices, current good manufacturing practices and current good clinical practices. We endeavor to stay abreast of changes to legislation and to ensure compliance. We have strengthened our team by establishing an in-house quality assurance department to ensure compliance. Experts at the EMA and FDA, as well as its consultants and CROs. We strive to develop good working relationships with regulators to ensure alignment on the selected clinical development and regulatory pathways to ensure optimal regulatory efficiencies are achieved. Furthermore, we seek to maintain a deep product candidate pipeline to allow us to potentially avoid being too dependent on the success of a single asset.
Nearly all aspects of our activities are subject to substantial regulation. No assurance can be given that any of our product candidates will fulfil regulatory compliance. Failure to comply with such regulations could result in delays, suspension, refusals and withdrawal of approvals, as well as fines.	We have established a robust quality management system to ensure compliance with current GLP, cGMP and current GCP. We endeavor to stay abreast of changes to legislation and to ensure compliance. We have strengthened our team by establishing an in-house quality assurance team to ensure compliance. We strive to develop good working relationships with regulators to ensure alignment on the selected clinical development and regulatory pathways to ensure optimal regulatory efficiencies are achieved. Furthermore, we seek to maintain a deep product candidate pipeline to allow us to potentially avoid being too dependent on the success of a single asset.

RISK FACTOR	MEASURES TAKEN TO CONTROL THESE RISKS
We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.	We endeavor to meet our contractual obligations and any relevant milestone achievements under our collaboration contracts. We endeavor to maintain a rich pipeline of possible collaboration partners as well as a good relationship 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.
We rely on patents and other intellectual property rights to protect our product candidates and platform technologies. Failure to enforce or protect these rights adequately could harm our ability to compete and impair our business.	We file and prosecute patent applications to protect our product candidates and technologies. We are doing this in close collaboration with leading expert firms in the field of intellectual property protection. In order to protect trade secrets, we maintain strict confidentiality standards and agreements with collaborating parties. We regularly monitor third-party intellectual property rights within our relevant fields and jurisdictions to avoid violating any third-party rights and secures licenses to such third-party rights on a need-to basis.
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 periodicalperiodic benchmark analyses with an external service provider to ensure the competitiveness of the compensation offered to our key personnel in comparison to other (peer group) companies. We pay close attention to creating an environment that supports the further development of the talents of our key people.

4.5.2 General Description of Our Risk Appetite

Our risk appetite serves as a guideline for us in deciding which 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.

4.5.3 Controlling Actions Taken by Us with Regard to Our Most Relevant Risks and Uncertainties

As required by Clause 2:391 sub 1 of the Dutch Civil Code in conjunction with Guideline 400.1.110c on Annual Reporting, 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”.

4.5.4 Material Impact of Risk Materialization in 2021

identified any material impact on argenx as a result of materialization of previously identified risks and uncertainties.

As set out in section 2.2.2 “Business interruptions resulting from the COVID-19 pandemic could cause a disruption of the development of our products and product candidates and adversely impact our business.”, we are monitoring the impact of the COVID-19 pandemic on our operations. We conduct our clinical trials globally, including in areas impacted by COVID-19 in North America, Europe and Japan. The continued spread of COVID-19 has and could continue to adversely impact our business and operations, including our or our third party partners’ discovery activities, preclinical studies and clinical trials.

4.5.5 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 its 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 Universal Registration Document), 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 financial 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.

argenx’s internal controls over financial reporting are a subset of internal controls and include those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of argenx;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of 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 of argenx are being made only by authorized persons; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of argenx’s assets that could have a material effect on the financial statements.

Since argenx has securities registered with the U.S. Securities and Exchange Commission (**SEC**) and is a large accelerated filer within the meaning of Rule 12b-2 of the U.S. Securities Exchange Act of 1934, argenx needs to assess the effectiveness of the internal controls over financial reporting and provide a report on the results of this 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 (**COSO**) and engaged an external advisor to help assess the effectiveness of those controls.

4.5.6 Recent or Current Developments in our System of Risk Management

In 2021, we have further increased our attention to pro-active risk management by making the evaluation of argenx’s core risks and uncertainties a standing discussion topic at our Board of Directors.

General description of the Company and it's Share Capital

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5 General description of the Company and its Share Capital

5.1 Legal Information on the Company

5.1.1 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 Willemstraat 5, 4811 AH, Breda, the Netherlands. Our telephone number is +31 (0) 10 70 38 441. Our website address is http://www.argenx.com. Information on the website does not form part of this Universal Registration Document and has not been scrutinized or approved by the AFM, unless that information is incorporated by reference into this Universal Registration Document (see also 9 "Information incorporated by reference").

Our European legal entity identifier number (**LEI**) is 7245009C5FZE6G9ODQ71. Our ordinary shares are listed on Euronext Brussels under ISIN Code NL0010832176 under the symbol "ARGX". The ADSs are listed on Nasdaq, under the symbol "ARGX".

5.1.2 Statutory / Corporate Objects

Pursuant to Article 3 of our Articles of Association, our corporate objects 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.

5.2 Share Capital

5.2.1 Authorized and Issued Share Capital

Under Dutch Law (Section 2:67 of the DCC), 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 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 March 1, 2022 our issued and paid up share capital amounted to €5,190,530.8, represented by 51,905,308 ordinary shares with a nominal value of €0.10, each representing an identical fraction of our share capital. As of March 1, 2022, neither we nor any of our subsidiaries held any of our own shares.

5.2.2 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 5,619,113 stock options (where each stock option entitles the holder to subscribe for one new ordinary share) were outstanding and granted as of December 31, 2021. Upon exercise of these 5,619,113 stock options, a total amount of $923.4 million in stock option exercise price would become payable to argenx by the optionees, increasing the argenx's share capital and share premium by the same amount. A total of 5,373,997 stock options (where each stock option entitles the holder to subscribe for one new ordinary share) were outstanding and granted as of March 1, 2022. Upon exercise of these 5,373,997 stock options, a total amount of $910.4 million in option exercise price would become payable to argenx by the optionees, increasing argenx's share capital by the same amount.

Further, we have granted restricted stock units which upon exercise will lead to an increase in the number of our outstanding shares. A total of 212,253 restricted stock units (where the holder receives restricted stock units receives the 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, 2021. A total of 212,253 restricted stock units (where the holder receives restricted stock units receives the 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 March 1, 2022.

Apart from the stock options and restricted stock units granted under the argenx Equity Incentive Plan, we do not currently have other stock options, restricted stock units, options to purchase securities, convertible securities or other rights to subscribe for or purchase securities outstanding. For stock option information through December 31, 2021, see note 14 "Share-based payments" in our consolidated financial statements in section 7 "Consolidated Financial Statements – audited as of and for the years ended December 31, 2021, 2020 and 2019".

5.2.3 History of Share Capital

New shares created during 2019
As a result of the exercise of options under the Equity Incentive Plan, 419,317 new shares were created in 2019.

On January 18, 2019, Johnson & Johnson Innovation JJDC, Inc. purchased 1,766,899 of our ordinary shares at a price of €100.02 per share, totaling €176.7 million, as part of a broader license and collaboration arrangement further described in 1.4.7 "Our Strategic Partnership with Janssen for cusatuzumab". The shareholding of Johnson & Johnson Innovation at the time of the issuance represented approximately 4.68% of our outstanding shares.

On November 7, 2019, we offered 4,000,000 of our ordinary shares through a global offering which consisted of (i) a public offering of 2,010,057 ADSs in the U.S. and certain other countries outside the EEA at a price of $121.00 per ADS, before underwriting discounts and commissions and offering expenses; and (ii) a concurrent private placement of 2,589,943

of ordinary shares in the EEA at an offering price of €109.18 per share, before underwriting discounts and commissions and offering expenses. On November 8, 2019, the underwriters of the offering exercised their over-allotment option to purchase 600,000 additional ADSs in full. As a result, we received $556.3 million of gross proceeds from this offering, decreased by $25.7 million of underwriter discounts and commissions, and offering expenses, of which $25.5 million has been deducted from equity. The total net cash proceeds from the offering amounted to $530.6 million.

As a result of these developments, argenx's share capital increased from 35,975,312 shares as of January 1, 2019 to 42,761,528 shares as of December 31, 2019.

New shares created during 2020
As a result of the exercise of options under the Equity Incentive Plan, 602,461 new shares were created in 2020.

On May 28, 2020, we offered 3,658,515 of our ordinary shares through a global offering which consisted of (i) a public offering of 2,584,138 ADSs in the U.S. and certain other countries outside the EEA at a price of $205.00 per ADS, before underwriting discounts and commissions and offering expenses; and (ii) a concurrent private placement of 1,074,377 ordinary shares in the EEA at an offering price of €186.52 per share, before underwriting discounts and commissions and offering expenses. On May 29, 2020, the underwriters of the offering exercised their over-allotment option to purchase 548,777 additional ADSs in full. As a result, we received $872.3 million of gross proceeds from this offering, decreased by $52.7 million of underwriter discounts and commissions, and offering expenses, of which $52.7 million has been deducted from equity. The total net cash proceeds from the offering amounted to $813.3 million.

As a result of these developments, argenx's share capital increased from 42,761,528 shares as of January 1, 2020 to 47,571,283 shares as of December 31, 2020.

New shares created during 2021
As a result of the exercise of options under the Equity Incentive Plan, 503,282 new shares were created in 2021.

On February 2, 2021, we offered 3,125,000 of our ordinary shares through a global offering which consisted of (i) a public offering of 1,608,000 ADSs in the U.S. and certain other countries outside the EEA at a price of $320.00 per ADS, before underwriting discounts and commissions and offering expenses; and (ii) a concurrent private placement of 1,517,000 ordinary shares in the EEA at an offering price of €265.69 per share, before underwriting discounts and commissions and offering expenses. On February 4, 2021, the underwriters of the offering exercised their over-allotment option to purchase 468,750 additional ADSs in full. As a result, we received $1,146.7 million of gross proceeds from this offering, decreased by $56.0 million of underwriter discounts and commissions, and offering expenses, of which $56.0 million has been deducted from equity. The total net cash proceeds from the offering amounted to $1,090.1 million.

The following table shows the developments in our share capital for the financial years 2021 and 2022 up to March 1, 2022:

Number of shares outstanding on December 31, 2019	**42,761,528**
Number of shares outstanding on December 31, 2020	**47,571,283**
Exercise of options in January 2021	108,785
Exercise of options in February 2021	21,184
Global offering on Nasdaq and Euronext on February 2, 2021	3,125,000
Over-allotment option exercised by underwriters on February 4, 2021	468,750
Exercise of options in March 2021	16,398
Exercise of options in April 2021	2,244
Exercise of options in May 2021	19,152
Exercise of options in June 2021	65,867
Exercise of options in July 2021	41,069
Exercise of options in August 2021	56,394
Exercise of options in September 2021	18,895
Exercise of options in October 2021	1,029
Exercise of options in November 2021	13,581
Exercise of options in December 2021	138,684
Number of shares outstanding on December 31, 2021	**51,668,315**
Exercise of options in January 2022	236,593
Exercise of options in February 2022	400
Number of shares outstanding on March 1, 2022	51,905,308

5.2.4 American Depository Shares

In connection with our IPO on Nasdaq, the Bank of New York Mellon, as depositary, registered and delivered American Depositary Shares, also referred to as 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 circumstances 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.

5.2.5 Issue of Shares

The Articles of Association provide that shares may be issued or rights to subscribe for our shares may be granted pursu¬ant to a resolution of the shareholders at the General Meeting, or alternatively, by our Board of Directors if so designated by the shareholders at the General Meeting. A resolution of the shareholders at the 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 the General Meeting. Designation by resolution of the shareholders at the General Meeting cannot be withdrawn unless determined otherwise at the time of designation. 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 the General Meeting and relates, at the most, to all unissued shares in argenx's 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 the 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.

On May 11, 2021, the shareholders at the 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 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.

5.2.6 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 the General Meeting may restrict or exclude the pre-emptive rights of shareholders. A resolution of the shareholders at the 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 the 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 the 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 the 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 the 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 5.2.5 "Issue of Shares" with respect to the current right of the Board of Directors to limit or exclude pre-emptive rights.

5.2.7 Acquisition of Shares in argenx's 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 the General Meeting.

As part of the authorization, the shareholders at the 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 the 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 the 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 a are subject to the right of usufruct

Lisa Ann

This is the story of Lisa Ann from Boston, New York

Lisa Ann was working as an owner of a small photography firm in Saratoga Springs, New York when she had her first autoimmune attack.

Patient Story

Since getting sick, Lisa Ann has spent a lot of time with other people diagnosed with pemphigus vulgaris. In these conversations, she also hears about the emotional stress for caregivers, which Lisa has not had to consider in her disease journey. Lisa Ann discusses her experience in tackling the disease without a regular caregiver:

“I didn‘t have a caregiver, so I didn‘t have to worry about somebody else‘s emotional connection. I didn‘t have somebody forcing me to get out of bed and go to work. If I didn‘t want to put clothes on because my whole back was raw, and a lot of my front was raw, that was fine. I kind of see it as an advantage that I lived alone, that I was able to not pull anybody into this drama.”

Live today, not in the future.

Finally having the pemphigus vulgaris diagnosis has led to some big changes in Lisa Ann’s life, including a new perspective on how she wants to live her life after many years of letting her symptoms and disease drive her decisions. Here is what she had to say on her ‘carpe diem’ attitude:

“You know, there‘s a difference between living your life the way you want to live it and living in fear all the time. I choose to live my life, which includes getting on the motorcycle and going and feeling that wind in my face and feeling the sun on my body. I choose to live this way because I could have died in my bedroom with half of my skin. I could have died on my bathroom floor but I didn‘t. I choose to live today, not in the future.“

or to a pledge in favor of a person other than us or its subsidiaries and the voting rights were vested in the pledgee or usufructuary before us or its 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.

5.2.8 Reduction of Share Capital

The shareholders at the General Meeting may, upon a proposal of 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 the 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 the General Meeting.

5.3 Share Classes and Principal Shareholders

As at March 1, 2022 the issued share capital of argenx SE amounts to €5,190,530.8 and is represented by 51,905,308 ordinary shares. There are only ordinary shares, 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.

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 member state of the European Union or an EEA 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.

As soon as the substantial holding or short position equals or exceeds 3% of the issued capital, the holder should report this. Subsequently, it should notify the AFM again when his 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%. Pursuant to a draft Dutch legislative proposal published for consultation on May 23, 2019 (the consultation period of which ended on July 4, 2021), a threshold of 2% may be added to this list, however, it is not yet clear if and when this change will enter into effect.
The duty to notify applies to legal entities as well as natural persons.

As of the date of this Universal Registration Document, 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 up to the date of this Universal Registration Document (see also section 5.2 "General Description of Share Capital" on page 207 and further). No shareholdings above 3% were reported to the Company directly.

The total number of stock options and restricted stock units outstanding as of March 1, 2022 amounts to 5,586,250.

At the date of this Universal Registration Document, 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.

At the date of this Universal Registration Document, as far as we are aware, there are no direct or indirect relationships between us and any of our significant shareholders.

Name of Beneficial Owner	Number of shares	Capital interest (percentage)	Number of voting rights	Voting rights (percentage)
T. Rowe Price Group, Inc.[1]	4,998,028[2]	11.68	4,927,064[3]	11.51
FMR LLC [1]	5,025,092[4]	9.80	5,025,092[4]	9.80
Artisan Investments GP LLC[1]	2,575,257[5]	5.02	2,575,257[5]	5.02
Federated Equity Management Company of Pennsylvania[1]	1,895,001[6]	4.97	1,895,001[6]	4.97
Johnson & Johnson Innovation – JJDC, Inc.[1]	1,766,899	4.66	1,766,899	4.66
The Vanguard Group[1]	1,978,464	4.16	0	0
BlackRock, Inc.[1]	2,397,921[8]	4.64	2,774,397[8]	5.37
Baillie Gifford & Co.[1]	0	0	2,966,216	6.24
Wellington Management Group LLP[1]	0	0	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 1,571 ordinary shares and 4,996,457 ADSs. There is a more recent SEC filing which sets out a number of 5,603,556 shares.
(3) Consisting of voting rights on 1,571 ordinary shares and 4,925,493 ADSs.
(4) There is a more recent SEC filing which sets out a number of 4,876,317 shares.
(5) Consisting of 105,864 ordinary shares and 2,469,393, according to the AFM filing, depository receipts and the respective number of voting rights. There is a more recent SEC filing which sets out a number of 3,180,665 shares.
(6) Consisting of 1,522,200 ordinary shares and 372,801 ADSs and the respective number of voting rights.
(7) Consisting of 1,718,968 ordinary shares and 678,953, according to the AFM filing, depository receipts.
(8) Consisting of voting rights on 2,050,038 ordinary shares and 724,359, according to the AFM filing, depository receipts
(9) Consisting of voting rights on 1,545,652 ordinary shares, 729,479 ADSs and 1,230 equity swaps.

5.4 General meeting of Shareholders and Voting Rights

The Articles of Association provide that he annual general meeting must be held on the second Tuesday of the month May. 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 Dutch Civil Code, 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 each 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 the 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.

Each shareholder (as well as other persons with voting rights or meeting rights) may attend the 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 the meeting, and they or their proxy have notified our Board of Directors of their intention to attend the meeting in writing at the address and by the date specified in the notice of the 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.

Resolutions of the general meeting are taken by an absolute majority, except where Dutch law or our Articles of Association provide for a qualified majority or unanimity.

One general meeting was held in 2021. The annual general meeting was held on May 11, 2021. In this meeting decisions were taken on the adoption of the new remuneration policy, the approval of the 2020 remuneration report, the adoption of the 2020 annual accounts, the allocation of losses in the financial year 2020, the release of the members of our Board of Directors from liability for their respective duties carried out in the financial year 2020, the appointment of Yvonne Greenstreet as non-executive director to our Board of Directors, the reappointment of Anthony Rosenberg as non-executive director to our Board of Directors, the authorization of our Board of Directors to issue shares and grant rights to subscribe for shares in our share capital up to a maximum of 10% of the outstanding capital at the date of the general meeting for a period of 18 months from the general meeting and to limit or exclude statutory pre-emptive rights, and the appointment of Deloitte Accountants B.V. as external auditor of argenx for the 2021 financial year.

5.5 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 previous financial year and the current financial year.

5.6 Amendments of Articles of Association

The shareholders at the General Meeting may resolve to amend the Articles of Association, at the proposal of our board of directors, with the consent of the majority of the non-executive directors. A resolution by the shareholders at the General Meeting to amend the Articles of Association requires a simple majority of the votes cast in a meeting in which at least half of our issued and outstanding capital is present or represented, or at least two-thirds of the votes cast, if less than half of our issued and outstanding capital is present or represented at that meeting.

Changing the rights of any of the shareholders will require the Articles of Association to be amended.

5.7 Obligations of Shareholders and Members of the Managing Board to Disclose Holdings

Shareholders may be subject to notification obligations under the DFSA. Pursuant to chapter 5.3 of the DFSA, any person who, directly or indirectly, acquires or disposes of an actual or potential capital interest and/or voting rights must immediately give written notice to the AFM of such acquisition or disposal by means of a standard form if, as a result of such acquisition or disposal, the percentage of capital interest and/or voting rights held by such person reaches, exceeds or falls below the following thresholds: 3%, 5%, 10%, 15%, 20%, 25%, 30%, 40%, 50%, 60%, 75% and 95%. Pursuant to a draft Dutch legislative proposal published for consultation on May 23, 2019 (the consultation period of which ended on July 4, 2021), a threshold of 2% may be added to this list, however, it is not yet clear if and when this change will enter into effect. In addition, any person whose capital interest or voting rights reaches, exceeds or falls below a threshold due to a change in our outstanding share capital, or in votes that can be cast on the shares as notified to the AFM by us, should notify the AFM no later than the fourth trading day after the AFM has published our notification of the change in its outstanding share capital.

Each person holding an interest in our share capital or voting rights of 3% or more at the time of admission of our shares to trading must immediately notify the AFM. Furthermore, every holder of 3% or more of our share capital or voting rights whose interest at 31 December at midnight differs from a previous notification to the AFM must notify the AFM within four weeks.

For the purpose of calculating the percentage of capital interest or voting rights, the following interests must be taken into account: (i) shares and/or voting rights directly held (or acquired or disposed of) by any person, (ii) shares and/or voting rights held (or acquired or disposed of) by such person's subsidiaries or by a third party for such person's account or by a third party with whom such person has concluded an oral or written voting agreement, (iii) voting rights acquired pursuant to an agreement providing for a temporary transfer of voting rights in consideration for a payment, and (iv) shares and/or voting rights which such person, or any controlled entity or third party referred to above, may acquire pursuant to any option or other right to acquire shares and/or the attached voting rights.

Special rules apply to the attribution of shares and/or voting rights that are part of the property of a partnership or other form of joint ownership. A holder of a pledge or right of usufruct in respect of shares can also be subject to notification obligations, if such person has, or can acquire, the right to vote on the shares. The acquisition of (conditional) voting rights by a pledgee or beneficial owner may also

trigger notification obligations as if the pledgee or beneficial owner were the legal holder of the shares and/or voting rights. We are required to notify the AFM promptly of any change of 1% or more in our issued and outstanding share capital or voting rights since the previous notification. The AFM must be notified of other changes in our issued and outstanding share capital or voting rights within eight days after the end of the quarter in which the change occurred. The AFM will publish all our notifications of our issued and outstanding share capital and voting rights in a public register. If a person's capital interest and/or voting rights reach, exceed or fall below the above-mentioned thresholds as a result of a change in our issued and outstanding share capital or voting rights, such person is required to make a notification not later than on the fourth trading day after the AFM has published our notification as described above.

Furthermore, each member of our Board of Directors and certain other persons who, inter alia, have (co-)managerial responsibilities, as well as certain persons closely associated with any such members or other persons, must immediately give written notice to the AFM by means of a standard form of any change in his or her holding of our shares and voting rights.

5.8 Short Positions

Each person holding a net short position amounting to 0.2% or more of the issued share capital of a Dutch listed company must report it to the AFM. Each subsequent increase of this position by 0.1% above 0.2% will also have to be reported. Each net short position equal to 0.5% of the issued share capital of a Dutch-listed company and any subsequent increase of that position by 0.1% will be made public via the AFM short selling register. To calculate whether a natural person or legal person has a net short position, their short positions and long positions must be set off. A short transaction in a share can only be contracted if a reasonable case can be made that the shares sold can actually be delivered, which requires confirmation of a third party that the shares have been located. There is also an obligation to notify the AFM of gross short positions. The notification thresholds are the same as apply in respect of the notification of actual or potential capital interests in the capital and/or voting rights, as described above.

The AFM keeps a public register of all notifications made pursuant to these disclosure obligations and publishes any notification received. In 2021, no short position was declared to the AFM.

5.9 Market Abuse Regime

The Market Abuse Regulation (Regulation EU nr. 596/2014, **MAR**) and related Commission Implementing Regulations and Delegated Regulations, provide for specific rules that intend to prevent market abuse, such as the prohibitions on insider trading, divulging inside information and tipping, and market manipulation (the **European Union Market Abuse Rules**). We are subject to the European Union Market Abuse Rules and non-compliance with these rules may lead to criminal fines, administrative fines, imprisonment or other sanctions.

The European Union Market Abuse Rules on market manipulation may restrict our ability to buy back its shares. In certain circumstances, our investors can also be subject to the European Union Market Abuse Rules. Pursuant to Article 19 MAR ("Managers' transactions"), members of our Board of Directors and any senior executive who has regular access to inside information relating directly or indirectly to us and has the power to take managerial decisions affecting the future developments and business prospects of us, (persons discharging managerial responsibilities, **PDMRs**), must notify the AFM of every transaction conducted on their own account relating to our shares or debt instruments or to derivatives or other financial instruments linked thereto.

In addition, certain persons closely associated with our PDMRs must also notify the AFM of every transaction conducted on their own account relating to our shares or debt instruments or to derivatives or other financial instruments linked thereto. MAR determines the following categories of persons: (i) the spouse or any partner considered by national law as equivalent to the spouse, (ii) dependent children, (iii) other relatives who have shared the same household for at least one year at the relevant transaction date and (iv) a legal person, trust or partnership, the managerial responsibilities of which are discharged by a person discharging managerial responsibilities or by a person referred to in point (i), (ii) or (iii), which is directly or indirectly controlled by such a person, which is set up for the benefit of such a person, or the economic interests of which are substantially equivalent to those of such a person. These notifications must be made no later than on the third business day following the transaction date and by means of a standard form. The notification may be postponed until the moment that the value of the transactions performed for the PDMR that person's own account, or transactions carried out by the persons closely associated with that person, reaches or exceeds an amount of €5,000 in the calendar year in question.

The AFM keeps a public register of all notifications under article 19 MAR. Third parties can request to be notified automatically by e-mail of changes to the public register. Pursuant MAR, we will maintain a list of its insiders. In addition, to further ensure compliance with MAR, we have adopted an internal policy relating to the possession of and transactions by members of our PDMRs and employees in our shares or in financial instruments of which the value is (co)determined by the value of our shares. Our Insider Trading Policy has been published on our website on https://www.argenx.com/investors/governance/rules-codes-compliance.

5.10 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 European Union 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 of 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 in accordance with the Belgian Act of May 2, 2007, the Belgian Royal Decree of November 14, 2007 and 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.

5.11 Dutch Financial Reporting Supervision Act

The Dutch Financial Reporting Supervision Act (*Wet toezicht financiële verslaggeving*) (the **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 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 Universal Registration Document also concerns the annual financial reporting within the meaning of 5:25c(2) DFSA.

5.12 Dividends and Other 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 our 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 incorporated into this URD by reference (see section 9 "Information incorporated by reference") contain the provision on the distribution of profits in its article 20 (Profits, distributions and losses).

5.13 Financial Calendar 2022

March 3, 2022	full year and fourth quarter 2021 financial results
May 5, 2022	first quarter 2022 financial results
May 10, 2022	annual general meeting
July 28, 2022	half year and second quarter 2022 financial results
October 27, 2022	third quarter 2022 financial results

6

Operating and Financial Review

Contents

6 Operating and Financial review

6.1 Overview

Since our inception in 2008, we have focused most of our financial resources and efforts towards developing our SIMPLE Antibody™ 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. We are advancing a deep pipeline of both clinical- and preclinical-stage product candidates for the treatment of neuromuscular, hematology, dermatology and nephrology indications within our growing commercial franchises. 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, 2021, we have raised an aggregate gross proceeds of $3,514.4 million, including:

i. an aggregate of $65.3 million (€46.0 million) from the private placement of equity securities in 2008, 2009 and 2011;
ii. $56.9 million (€41.8 million) from our initial public offering on the Euronext Brussels in 2014;
iii. $50.9 million (€46.0 million) from the private placement of equity securities, primarily to U.S. based institutional investors, in 2016;
iv. $114.7 million from our initial U.S. public offering on the Nasdaq Global Select Market in May 2017;
v. $265.5 million from our second U.S public offering on the Nasdaq Global Select Market in December 2017;
vi. $300.6 million from our third U.S public offering on the Nasdaq Global Select Market in September 2018;
vii. $200.9 million (€176.7 million) from the private placement of equity securities as part of the closing of the global collaboration and license agreement with Janssen in January 2019;
viii. $556.3 million (€502.2 million) from a global offering in November 2019;
ix. $590.5 million from our U.S. public offering on the Nasdaq Global Select Market and $222.8 million (€200.4 million) from a concurrent private placement in May 2020; and
x. $1,090.1 million from from our U.S. public offering on the Nasdaq Global Select Market in January 2021.

In addition, as of December 31, 2021, we have received upfront payments, milestone payments and research and development service fees from our collaborators totaling $578.9 million. As of December 31, 2021, we had cash, cash equivalents and current financial assets of $2,336.7 million.

Our balance sheet shows our total assets accumulate to $2,850.3 million for the year ended December 31, 2021, compared to $2,279.4 million for the year ended December 31, 2020 and $1,610.2 million for the year ended December 31, 2019. The main reason for the material change in balance sheet total are the various equity financing rounds (described in section 5.2.3 “History of Share Capital”), completed over the period covered by the financial statements incorporated herein by reference (see section 9 “Information incorporated by reference”).

Since our inception, we have incurred significant operating losses. 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 antibody positive. On January 20, 2022, the Japan 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. These are the only approved products we currently have and we have not generated any revenue from product sales until the end of the financial year ended December 31, 2021.

Our ability to generate revenue sufficient to achieve profitability will depend significantly upon the successful commercialization of our approved product and development and eventual commercialization of one or more of our product candidates. For the years ended December 31, 2021 and 2020, we incurred total comprehensive losses of $450.6 million and $446.2 million, respectively. As of December 31, 2021, we had accumulated losses of $1,400.2 million.

We expect our expenses to increase substantially in connection with our further transition to an integrated immunology company, including the further build-out of global commercial infrastructure and drug product inventory in light of the global launch of VYVGART™ for the treatment of gMG, the advancement of our clinical-stage pipeline, including ongoing registrational trials across four indications of efgartigimod, and continued investment in our IIP. In addition, we expect to continue to incur significant costs associated with operating as a public company in the U.S. We anticipate that our expenses will increase substantially if and as we:

Research and Development activities:
- execute the Phase 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 that successfully complete clinical trials.

Pre-commercial and commercial activities
- further build-out our sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize VYVGART™ for which we obtained the regulatory approval from FDA and the PMDA and any product candidate for which we may obtain approval; and
- expand our global reach enabling us to commercialize any product candidates 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 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.

6.2 Basis of Presentation

6.2.1 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 reflects 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.

6.2.2 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.

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, the following five steps are performed:

1. Identify the contracts
In its current collaboration and license agreements, the Company is mainly licensing its intellectual property and/or providing research and development products and 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 the agreement, 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, as described in section 1.4.2 "Our Strategic Partnership with Zai Lab for efgartigimod"), 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 other material collaboration and license agreements, the Company has 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.

- 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.

- 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.

- 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.

- 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 de 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, as described in section 1.4.2 "Our Strategic Partnership with Zai Lab for efgartigimod") contains more than one performance obligation, the Company assesses to allocate the transaction price to all performance obligation 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 agreements (i.e., the Zai Lab Agreement, as described in section 1.4.2 "Our Strategic Partnership with Zai Lab for efgartigimod") contains more than one performance obligation, the Company recognized revenue at point in time for transfer of license and the Company recognizes revenue over time for supply of clinical and commercial products as 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, 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.

6.2.3 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, the Company entered into a license agreement with AgomAb for the use of HGF-mimetic SIMPLE Antibodies™, developed under the Company's IIP. In exchange for granting this license, the Company received a profit share in AgomAb.

In March 2021, AgomAb secured $74.0 million in Series B financing by issuing 286,705 Preferred B Shares. argenx 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. The fair value of non-current financial assets is updated at the end of each reporting period.

6.2.4 Research and Development Expenses

Research and development expenses consist principally of:

- personnel expense related to compensation of research and development staff and related expenses, including salaries, benefits and share-based compensation expenses;
- 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 contract research organizations in connection with preclinical testing and the performance of clinical trials for our product candidates and (iii) costs associated with regulatory submissions and approvals, quality assurance and pharmacovigilance;
- 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.

The following table shows our research and development expenses for the past three financial years:

	Financial year ended December 31,		
(In USD thousands)	2021	2020	2019
Research and development expenses	580,520	370,885	220,771

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 Janssen, we assumed certain development obligations, and were jointly responsible with Janssen for all research, development and regulatory costs relating to the product. Under our agreement with Zai, we are responsible for certain costs relating to future clinical trials involving efgartigimod conducted partially by Zai.

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 chapter 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 (except for the U.S. and Japan), 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 United States 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.

6.2.5 Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of (i) 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, (ii) professional fees for business development, marketing, IT, audit, commercial, legal services and investor relations costs, (iii) board expenses consisting of directors' fees, travel expenses and share-based compensation for non-executive board members, (iv) costs associated with preparation of commercial launch of VYVGART™ for the treatment of gMG in the U.S. and promotional activities (v) costs associated with the preparation of the commercial launch in Japan and EMEA and continued investment in supply chain, (vi) allocated facilities costs and (vii) 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 and operate as a public company in the U.S. Such costs include increases in our finance and legal personnel, additional external legal and audit fees, and expenses and costs associated with compliance with the regulations governing public companies. We expect our selling and marketing expenses to increase significantly due to marketing and promotional activities with respect to the commercial launch of VYVGART™ in the U.S. and Japan.

6.2.6 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.

6.2.7 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 Universal Registration Document. For more information on currency exchange fluctuations on our business, please see 2.7.5 "Exchange rate fluctuations or abandonment of the euro currency may materially affect our results of operations and financial condition.". We have no derivative financial instruments to hedge interest rate and foreign currency risk.

6.2.8 Income Tax Expense

We have a history of losses. We expect to continue incurring 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 recent regulatory approval by the FDA and the PMDA. Consequently, we do not have any deferred tax asset regarding unused tax losses on our consolidated statements of financial position.

We are incurring 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.

6.3 Capitalization and Indebtedness

The table below sets forth our capitalization as of December 31, 2021 on an actual basis:

(In USD thousands)	As at December 31, 2021 (audited)
Total current debt (including current portion of non-current debt)	**0**
Guaranteed	0
Secured	0
Unguaranteed / unsecured	0
Total non-current debt (excluding current portion of non-current debt)	**0**
Guaranteed	0
Secured	0
Unguaranteed / unsecured	0
Shareholder equity	**2,534,224**
Share capital	6,233
Share premium	3,462,775
Legal reserve(s)(1)	131,684
Retained earnings	(1,400,197)
Other reserves	333,729
Total	**2,534,224**

(1) Legal reserves are the amount of translation differences.

The table below sets forth our indebtedness as of December 31, 2021 on an actual basis:

(In USD thousands)	As at December 31, 2021 (audited)
A. Cash	**242,494**
B. Cash equivalents[1]	**1,092,182**
C. Other current financial assets[2]	**1,002,052**
D. Liquidity (A)+(B)+(C)	**2,336,728**
E. Current financial debt (including debt instruments, but excluding current portion of non-current financial debt)	**0**
F. Current portion of non-current financial debt[3]	**3,509**
G. Current financial indebtedness (E + F)	**3,509**
H. Net current financial indebtedness (G - D)	**(2,333,219)**
I. Non-current financial debt (excluding current portion and debt instruments)[3]	**7,956**
J. Debt instruments	**0**
K. Non-current trade and other payables	**0**
L. Non-current financial indebtedness (I)+(J)+(K)	**7,956**
M. Total financial indebtedness (H)+(L)	**(2,325,263)**

(1) See note 12 "Cash and cash equivalents" to our consolidated financial statements in section 7 "Consolidated Financial Statements – audited as of and for the years ended December 31, 2021, 2020 and 2019".
(2) See note 11 "Financial assets – current" to our consolidated financial statements in section 7 "Consolidated Financial Statements – audited as of and for the years ended December 31, 2021, 2020 and 2019".
(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 7 "Consolidated Financial Statements – audited as of and for the years ended December 31, 2021, 2020 and 2019".

As of December 31, 2021, current financial debt (as disclosed in item E. in the table above) included current liabilities related to short-term leases in the amount of $3.5 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 $8.0 million.

More information is included in our consolidated financial statements and related notes included in section 7 “Consolidated Financial Statements – audited as of and for the years ended December 31, 2021, 2020 and 2019”.

6.4 Critical Accounting Policies and Significant Judgments and Estimates

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.

6.4.1 Critical estimates in applying accounting policies

The following areas are areas where key assumptions concerning the future, and other key sources of estimation uncertainty at the end of the reporting period, have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year.

Research and development cost accruals

The Company recognizes costs of $163.7 million, as specified in note 15 “Trade and other payables” to the consolidated financial statements, incurred for clinical trial activities and manufacturing of drug products, as research and development expenses based on an evaluation of its vendors’ progress toward completion of specific tasks. Timing of payment may differ significantly from the period in which the costs are recognized as expense, resulting in clinical trial accruals recognized within “Trade and other payables” in the consolidated statements of financial position.

Quantification of the research progress and the translation of the progress to these accruals requires estimates, because the progress is not directly observable. In estimating the vendors’ progress toward completion of specific tasks, the Company therefore uses non-financial data such as patient enrollment, clinical site activations and vendor information of actual costs incurred. This data is obtained through reports from or discussions with Company personnel and outside service providers as to the progress or state of completion of trials, or the completion of services. Costs are expensed over the service period the services are provided. Costs for services provided that have not yet been paid are recognized as accrued expenses.

6.5 Results of Operation

Below is the comparison of the consolidated statements of profit or loss for the financial years ended December 31, 2021, 2020 and 2019.

	Financial year ended December 31,			% change (2021 compared to 2020)
(In USD thousands, unless otherwise indicated)	2021	2020	2019	
Revenue	497,277	41,243	78,462	1,106
Other operating income	42,141	23,668	15,563	78
Total operating income	**539,418**	**64,911**	**94,025**	**731**
Research and development expenses	(580,520)	(370,885)	(220,771)	57
Selling, general and administrative expenses	(307,644)	(171,643)	(72,146)	79
Total operating expenses	**(888,164)**	**(542,528)**	**(292,917)**	**64**
Operating loss	**(348,746)**	**(477,617)**	**(198,892)**	**(27)**
Financial income /(expenses)	(944)	(1,501)	15,983	(37)
Exchange gains (losses)	(50,053)	(126,234)	6,990	(60)
Loss before taxes	**(399,743)**	**(605,352)**	**(175,919)**	**(34)**
Income tax expense	(8,522)	(3,103)	(5,289)	175
Loss for the year	**(408,265)**	**(608,455)**	**(181,208)**	**(33)**
Weighted average number of shares outstanding	51,075,827	45,410,442	38,619,121	12
Basic and diluted loss per share (in USD)	(7.99)	(13.40)	(4.69)	(40)

6.5.1 Revenue

	Financial year ended December 31,			% change (2021 compared to 2020)
(In USD thousands)	2021	2020	2019	
Zai Lab	151,903	—	—	100
Janssen	292,279	33,759	22,386	766
AbbVie	121	565	855	(79)
Agomab	—	—	1,684	
Other	—	38	50	(100)
Upfront payments	**444,303**	**34,362**	**24,975**	**1,193**
Zai Lab	25,634	—	—	100
Janssen	22,865	2,641	1,738	766
AbbVie	102	762	30,077	(87)
Other	1,214	19	25	6,289
Milestone payments	**49,815**	**3,422**	**31,840**	**1,356**
Janssen	2,028	3,175	21,236	(36)
Other	298	284	411	5
Research and development service fees	**2,326**	**3,459**	**21,647**	**(33)**
Zai Lab	833	—	—	100
Other revenues	**833**	**—**	**—**	**100**
Total revenue	**497,277**	**41,243**	**78,462**	**1,106**

Kim

“ Some days I think my current treatments control my disease, and just when I feel like things are smooth sailing, my symptoms come rushing back.”

Our revenue increased by $456.1 million to $497.3 million for the year ended December 31, 2021, compared to $41.2 million for the year ended December 31, 2020, a result of the recognition of the transaction price as a consequence of the termination of the collaboration agreement with Janssen and the closing of the strategic collaboration for efgartigimod with Zai Lab.

The increase in revenue recognition from upfront payments is 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 increase in revenue recognition from milestone payments is mainly due to the recognition of $25.0 million from Zai Lab upon regulatory approval of efgartigimod by FDA in the U.S. and the recognition of $22.9 million as a result of the termination of the collaboration agreement with Janssen.

The decrease in revenue recognition from research and development service fees of $1.1 million is primarily driven by the decrease due to the termination of the collaboration agreement with Janssen.

6.5.2 Other Operating Income

	Financial year ended December 31,			% change (2021 compared to 2020)
(In USD thousands)	2021	2020	2019	
Grants	4,398	1,365	2,563	222
Research and development incentives	13,970	10,257	5,373	36
Payroll tax rebates	12,621	9,095	6,413	39
Change in fair value on non-current financial assets	11,152	2,951	1,214	278
Total	**42,141**	**23,668**	**15,563**	**78**

Other operating income increased by $18.4 million to $42.1 million for the year ended December 31, 2021, compared to $23.7 million for the year ended December 31, 2020. The increase is primarily driven by

- the increase in research and development incentives, as a result of the increased research and development costs incurred;
- the increase in payroll tax rebates, as a direct result of the increase in the employment of highly qualified research and development personnel, eligible for specific payroll tax rebates; and
- the increase in fair value on our profit share in AgomAb Therapeutics NV.

For more information regarding governmental policies that could affect our operations, see 1.9 “Regulation”.

6.5.3 Research and Development Expenses

	Financial year ended December 31,			% change (2021 compared to 2020)
(In USD thousands)	2021	2020	2019	
Personnel expenses	160,464	86,036	51,172	87
External research and development expenses	382,902	259,943	152,889	47
Materials and consumables	2,735	3,562	2,267	(23)
Depreciation and amortization	3,742	2,835	1,840	32
Other expenses	30,677	18,509	12,603	66
Total	**580,520**	**370,885**	**220,771**	**57**

Our research and development expenses totaled $580.5 million and $370.9 million for the years ended December 31, 2021 and 2020, respectively. The increase of $209.6 million compared to 2020 primarily results from an increase in external research and development expenses and personnel expenses, primarily related to the efgartigimod program in various indications and other clinical and preclinical programs. Furthermore, the personnel expenses increased due to a planned increase in headcount.

The increase of $74.4 million in personnel expense for the year ended December 31, 2021 corresponded primarily to (i) an increase of $49.2 million for share-based compensation expenses related to the grant of stock options to our research and development employees, and (ii) increased costs associated with additional research and development personnel. We employed on average 349.7 full time equivalents in our research and development functions in the year ended December 31, 2021, compared to 213.0 in the year ended December 31, 2020.

Our external research and development expenses for the year ended December 31, 2021 totaled $382.9 million, compared to $259.9 million for the year ended December 31, 2020. The increase reflects higher 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:

	Financial year ended December 31,			% change (2021 compared to 2020)
(In USD thousands)	2021	2020	2019	
efgartigimod	311,038	182,511	94,024	70
cusatuzumab	24,630	48,796	43,139	(50)
Other programs	47,234	28,636	15,726	65
Total	**382,902**	**259,943**	**152,889**	**47**

External research and development expenses for our lead product candidate efgartigimod totaled $311.0 million for the year ended December 31, 2021, compared to $182.5 million for the year ended December 31, 2020. This increase of $128.5 million corresponds primarily to increased manufacturing and clinical development activities in relation to:

- the execution of two Phase 3 clinical trials in MG;
- the execution of the bridging study for ENHANZE® efgartigimod in MG;
- the execution of two Phase 2 clinical trials and initiation of the Phase 3 clinical trial in CIDP;
- the execution of two Phase 3 clinical trials in ITP;
- the execution of the Phase 2 clinical trial and initiation of the Phase 3 clinical trial in PV and PF;
- the execution of Phase 2 clinical trial in BP; and
- the execution of Phase 1 clinical trial in Myositis.

External research and development expenses for cusatuzumab totaled $24.6 million for the year ended on December 31, 2021 compared to $48.8 million for the year ended December 31, 2020. This decrease of $24.2 million is the result of the termination of the collaboration agreement with Janssen.

External research and development expenses on other programs increased by $18.6 million to $47.2 million for the year ended December 31, 2021, compared to $28.6 million for the year ended December 31, 2020. The increase is primarily due to increased research and development expenses in relation to the advancement of our ARGX-117 program, a complement-targeting antibody against C2.

6.5.4 Selling, General and Administrative Expenses

(In USD thousands)	Financial year ended December 31, 2021	2020	2019	% change (2021 compared to 2020)
Personnel expenses	164,646	108,507	44,774	52
Professional fees	102,674	48,681	18,181	111
Supervisory board	12,958	4,838	3,127	168
Other expenses	27,366	9,617	6,064	185
Total	**307,644**	**171,643**	**72,146**	**79**

Our selling, general and administrative expenses totaled $307.6 million and $171.6 million for the years ended December 31, 2021 and 2020, respectively. The increase in our selling, general and administrative expenses for the year ended December 31, 2021 was principally due to an increase of personnel expense and professional fees, resulting from:

- increased costs of the share-based payment compensation plans related to the grant of stock options to our selling, general and administrative employees;
- increased costs associated with additional employees recruited to strengthen our selling, general and administrative activities, in preparation of the commercial launch of VYVGART™ in the U.S.;
- increased professional fees, primarily in preparation of the commercial launch of VYVGART™ in the U.S.; and
- Promotional and marketing cost associated with the commercial launch of VYVGART™, following the approval by FDA in the U.S.

We employed on average 264.4 full time equivalents in our selling, general and administrative functions in the year ended December 31, 2021, compared to 119.5 in the year ended December 31, 2020.

6.5.5 Financial Income (Expense)

For the year ended December 31, 2021, financial expense amounted to $0.9 million compared to $1.5 million for the year ended December 31, 2020. The decrease of $0.6 million in 2021 related primarily to higher financial expenses incurred in 2020 as a result of a decrease in net asset value on current financial assets following the impact of the COVID-19 outbreak on the financial markets, partly offset by the interest received on our cash and cash equivalents and current financial assets.

6.5.6 Exchange Gains (Losses)

Exchange losses totaled $50.1 million for the year ended December 31, 2021, compared to exchange losses of $126.2 million for the year ended December 31, 2020. The decrease was mainly attributable to unrealized exchange rate losses on the cash, cash equivalents and current financial assets position in Euro during the financial year ended December 31, 2021 as compared to unrealized exchange rate losses on the cash, cash equivalents and current financial assets position in USD during the financial year ended December 31, 2020.

6.6 Liquidity and Capital Resources

6.6.1 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 but have not generated any significant revenue from product sales. 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, 2021, we have raised gross proceeds of $3,514.4 million from private and public offerings of equity securities and received $578.9 million in revenue from our collaborators.

Our cash flows may fluctuate and are difficult to forecast and will depend on many factors. On December 31, 2021, we had cash, cash equivalents and current financial assets of $2,336.7 million, compared to $1,996.5 million on December 31, 2020.

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 which are detailed in note 29 “Commitments” to our consolidated financial statements in section 7 “Consolidated Financial Statements – audited as of and for the years ended December 31, 2021, 2020 and 2019”.

For more information as to the risks associated with our future funding needs, see the section of this annual report titled 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 management” to our consolidated financial statements in section 7 “Consolidated Financial Statements – audited as of and for the years ended December 31, 2021, 2020 and 2019”.

6.6.2 Cash Flows

The table below summarizes our cash flows for the years ended December 31, 2021, 2020 and 2019.

(In USD thousands)	Financial year ended December 31, 2021	2020	2019	Variance 2021 compared to 2020
Cash and cash equivalents at beginning of the period	1,216,803	372,162	321,791	844,641
Net cash flows (used in)/ from operating activities	(606,812)	(398,463)	151,630	(208,349)
Net cash flows (used in)/ from investing activities	(347,070)	344,692	(833,267)	(691,762)
Net cash flows (used in)/ from financing activities	1,121,342	833,003	733,726	288,339
Effect of exchange rate differences on cash and cash equivalents	(49,587)	65,409	(1,717)	(114,996)
Cash and cash equivalents at end of the period	**1,334,676**	**1,216,803**	**372,162**	**117,873**

Net Cash Used in Operating Activities

Net cash outflow from our operating activities increased by $208.3 million to a net outflow of $606.8 million for the year ended December 31, 2021, compared to a net outflow of $398.5 million for the year ended December 31, 2020. The net cash outflow from operating activities for the year ended December 31, 2021 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 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. The net cash outflow of $398.5 million for the year ended December 31, 2020 was primarily influenced by (i) the research and development expenses incurred in relation to the manufacturing and clinical development activities of efgartigimod, cusatuzumab and the advancement of other preclinical and discovery-stage product candidate, (ii) the personnel expenses and consulting expenses incurred in preparation of the potential commercial launch of efgartigimod in the U.S., and (iii) the manufacturing of pre-launch inventory ahead of the potential commercial launch of efgartigimod in the U.S.

Net Cash Used in / from Investing Activities
Investing activities for the year ended December 31, 2021, consist primarily of the divestment of current financial assets and the purchase of intangible assets. Cash flow from investing activities represented a net outflow of $347.1 million for the year ended December 31, 2021, compared to a net inflow of $344.7 million for the year ended December 31, 2020. The net outflow for the year ended December 31, 2021 related primarily to (i) the net investment of $228.2 million in current financial assets, including money market funds and term deposit accounts, compared to a net divestment of $341.9 million for the year ended December 31, 2020 and (ii) the cash outflow of $98.0 million during 2021 in relation to the purchase of a PRV from Bayer Healthcare Pharmaceuticals.

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 $1,121.3 million for the year ended December 31, 2021, compared to a net cash inflow of $833.0 million for the year ended December 31, 2020. The net cash inflow for the year ended December 31, 2021 was attributed to (i) $1,091.7 million net cash proceeds from our global offering in February 2021, compared to $812.6 million net cash proceeds from our global offering and concurrent private placement in May 2020 and (ii) $33.4 million proceeds received from the exercise of stock options in 2021, compared to $22.9 million for the year ended 2020.

Operating and Capital Expenditure Requirements
We have never achieved profitability and, as of December 31, 2021, we had accumulated losses of $1,400.2 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 commercialization of efgartigimod in the U.S. and Japan, and seek to obtain regulatory approval and commercialization of our product candidates in Europe.

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. 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 ahead of 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 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;
- the amount of revenues, if any, we may derive either directly or in the form of royalty payments from future sales of our product candidates, if approved;
- 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 the section of this annual report titled 2.1 “Risk Factors Related to argenx’s Financial Position and Need for Additional Capital”.

6.6.3 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 Universal Registration Document.

6.7 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.

6.8 Contractual Obligations

Below an overview is given of our material contractual obligations at December 31, 2021:

	Payments due by period				
(In USD thousands)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Lease liabilities	12,004	3,509	6,331	2,164	—
Lease commitments not commenced	19,155	—	—	1,437	17,718

We signed lease agreements for laboratory and office space in Zwijnaarde, Belgium, offices in Breda, Netherlands, Boston, U.S., and Tokyo, Japan, as disclosed in note 6 “Property, Plant and Equipment” in the consolidated financial statements in section 7 “Consolidated Financial Statements – audited as of and for the years ended December 31, 2021, 2020 and 2019”.

In January 2021, we have 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 $1.9 million, which would be operational in the second quarter of 2025, and with an initial term of 10.5 years. Included in the binding lease commitment is a rent free period of 6 months following the completion of the building. The total future cash outflows related to this lease are represented above as “Lease commitments not commenced”.

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 7 “Consolidated Financial Statements – audited as of and for the years ended December 31, 2021, 2020 and 2019”.

6.9 Financial Statements

The (consolidated) audited financial statements of the Company for the financial years ending on December 31, 2020 and 2019 are incorporated into this Universal Registration Document by reference. Please see section 9 “Information incorporated by reference”.

6.10 Information Regarding the Independent Auditor

The audited consolidated financial statements as of and for the financial years ended December 31, 2021 and 2020 and 2019 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.

6.11 Material Contracts and Related Party Transactions

6.11.1 Material Contracts

Our material contracts are described in chapter 1.4 “Collaboration Agreements”, 1.5 “License Agreements” and 1.6 “Distribution Agreements”.

6.11.2 Related Party Transactions

Since December 31, 2021, being the end of the last financial period for which audited financial statements have been published, 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, in the period covered by the financial statements incorporated herein by reference, 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 paragraph 5.3 “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 is 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 Chief Executive Officer. The Chief Executive Officer is our sole executive director. The key terms of his agreement are as follows:

Tim Van Hauermeiren	
Fixed base compensation	$651,986
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]	$26,894
Duration	Indefinite

(1) Amounts shown represent pension contributions paid during the year-ended December 31, 2021.

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. His employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least twelve months.

Keith Woods, our Chief Operating Officer, has an employment contract with our subsidiary, argenx US Inc., for an indefinite term. His employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least twelve months.

Wim Parys, our Chief Medical Officer, has an employment contract with our subsidiary argenx BV, for an indefinite term. His employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least twelve months.

Hans de Haard, our Chief Scientific Officer, has an employment contract with our subsidiary, argenx BV, for an indefinite term. His employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least twelve months.

Arjen Lemmen, our VP Corporate Development & Strategy, has an employment contract with our subsidiary, argenx BV, for an indefinite term. His employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least twelve months.

Dirk Beeusaert, our General Counsel until December 31, 2021, had an employment contract with our subsidiary, argenx BV, for an indefinite term. This agreement was terminated with mutual agreement with effect from December 31, 2021.

Andria Wilk, our Global Head of Quality, has an employment contract with our subsidiary, argenx BV, for an indefinite term. Her employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least twelve months.

Malini Moorthy, our General Counsel, joined argenx in 2022 and has an employment contract with our subsidiary, argenx US Inc., for an indefinite term. Her employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least twelve months.

Luc Truyen, our Head of Research and Development Management Operations and, from April 1, 2022 on, our Chief Medical Officer, has an employment contract with our subsidiary, argenx BV, for an indefinite term. His employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least twelve months.

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 Securities Act and is therefore unenforceable.

6.12 Employees

As of December 31, 2021, we had 650 employees (excluding consultants) At each date shown below, we had the following number of employees, broken out by department and geography.

	As at December 31,			As at March 1
(In USD thousands)	2021	2020	2019	2022
Function				
Research and development	289	193	118	307
Selling, general and administrative	361	143	70	377
Geography				
Zwijnaarde, Belgium	296	213	145	308
Boston, U.S.	276	108	40	284
Tokyo, Japan	57	13	3	63
Breda, the Netherlands	–	–	–	–
Geneva, Switzerland	9	2	–	10
Issy Les Moulineaux, France	3	–	–	6
Munich, Germany	9	–	–	13
Toronto, Canada	–	–	–	–
Total	**650**	**336**	**188**	**684**

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 industry level CBAs that relate to the chemical industry. 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.

6.13 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.

6.14 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.

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Consolidated Financial Statements

CONSOLIDATED FINANCIAL STATEMENTS – AUDITED AS OF AND FOR THE YEARS ENDED DECEMBER 31, 2021, 2020 AND 2019

Contents

Consolidated Statements of Financial Position

Assets (In USD thousands $)	Note	As of December 31, 2021	As of December 31, 2020(*)	As of December 31, 2019(*)
Current assets				
Cash and cash equivalents	12	1,334,676	1,216,803	372,162
Research and development incentive receivables — current		—	463	293
Financial assets — current	11	1,002,052	779,649	1,128,499
Prepaid expenses		58,946	27,913	10,136
Trade and other receivables	10	38,221	6,978	31,585
Inventories	9	109,076	25,195	—
Total current assets		**2,542,971**	**2,057,001**	**1,542,675**
Non-current assets				
Other non-current assets	7	54,876	7,816	3,624
Research and development incentive receivables — non-current		32,707	20,626	9,624
Deferred tax asset	8	32,191	15,038	—
Property, plant and equipment	6	15,844	11,582	9,175
Intangible assets	5	171,684	167,344	45,117
Total non-current assets		**307,303**	**222,406**	**67,540**
Total assets		**2,850,274**	**2,279,407**	**1,610,215**

* The Company has adopted a change in its presentation currency from EUR to USD at January 1, 2021, as described in note 3.4.4. Accordingly, the December 31, 2020 and December 31, 2019 comparative statements of financial position and related notes have been re-presented retrospectively based on the accounting policies as outlined in note 3.4.4.

The accompanying notes form an integral part of these consolidated financial statements.

Consolidated Statements of Financial Position

Equity and Liabilities (In thousands of $)	Note	As of December 31, 2021	As of December 31, 2020(*)	As of December 31, 2019(*)
Equity	13			
Equity attributable to owners of the parent				
Share capital		6,233	5,744	5,209
Share premium		3,462,775	2,339,033	1,505,641
Translation differences		131,684	134,732	(27,541)
Accumulated losses		(1,400,197)	(991,932)	(383,477)
Other reserves		333,729	186,474	80,577
Total equity		**2,534,224**	**1,674,051**	**1,180,409**
Non-current liabilities				
Provisions for employee benefits		417	156	72
Lease liabilities — non-current	22	7,956	6,181	5,101
Deferred tax liabilities	8	6,438	1,487	—
Deferred revenue — non-current	16	—	269,039	244,937
Total non-current liabilities		**14,811**	**276,863**	**250,110**
Current liabilities				
Lease liabilities — current	22	3,509	3,476	2,218
Trade and other payables	15	293,415	275,192	95,827
Tax liabilities		4,315	3,497	386
Deferred revenue — current	16	—	46,328	81,265
Total current liabilities		**301,239**	**328,493**	**179,696**
Total liabilities		**316,050**	**605,356**	**429,806**
Total Equity and Liabilities		**2,850,274**	**2,279,407**	**1,610,215**

* The Company has adopted a change in its presentation currency from EUR to USD at January 1, 2021, as described in note 3.4.4. Accordingly, the December 31, 2020 and December 31, 2019 comparative statements of financial position and related notes have been re-presented retrospectively based on the accounting policies as outlined in note 3.4.4.

The accompanying notes form an integral part of these consolidated financial statements.

Consolidated Statements of Profit or Loss

(In USD thousands $ except for shares and EPS)	Note	Year Ended December 31, 2021	Year Ended December 31, 2020(*)	Year Ended December 31, 2019(*)
Revenue	16	497,277	41,243	78,462
Other operating income	17, 7	42,141	23,668	15,563
Total operating income		**539,418**	**64,911**	**94,025**
Research and development expenses	19	(580,520)	(370,885)	(220,771)
Selling, general and administrative expenses	20	(307,644)	(171,643)	(72,146)
Total operating expenses		**(888,164)**	**(542,528)**	**(292,917)**
Operating loss		**(348,746)**	**(477,617)**	**(198,892)**
Financial income/(expense)	23	(944)	(1,501)	15,983
Exchange gains/(losses)	23	(50,053)	(126,234)	6,990
Loss before taxes		**(399,743)**	**(605,352)**	**(175,919)**
Income tax expense	24	(8,522)	(3,103)	(5,289)
Loss for the year		**(408,265)**	**(608,455)**	**(181,208)**
Loss for the year attributable to:				
Owners of the parent		(408,265)	(608,455)	(181,208)
Weighted average number of shares outstanding		51,075,827	45,410,442	38,619,121
Basic and diluted loss per share (in $)	25	(7.99)	(13.40)	(4.69)

* The Company has adopted a change in its presentation currency from EUR to USD at January 1, 2021, as described in note 3.4.4. Accordingly, the December 31, 2020 and December 31, 2019 comparative statements of profit and loss and related notes have been re-presented retrospectively based on the accounting policies as outlined in note 3.4.4.

The accompanying notes form an integral part of these consolidated financial statements.

Consolidated Statements of Comprehensive Income/Loss

(In USD thousands $ except for shares)	Note	Year Ended December 31, 2021	Year Ended December 31, 2020(*)	Year Ended December 31, 2019(*)
Loss for the year		**(408,265)**	**(608,455)**	**(181,208)**
Items that may be reclassified subsequently to profit or loss, net of tax				
Currency translation differences, arisen from translating foreign activities		(3,048)	—	—
Translation effect		—	162,273	(8,587)
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	(39,290)	—	—
Other comprehensive loss, net of income tax		**(42,338)**	**162,273**	**(8,587)**
Total comprehensive loss attributable to:				
Owners of the parent		(450,603)	(446,182)	(189,795)

* The Company has adopted a change in its presentation currency from EUR to USD at January 1, 2021, as described in note 3.4.4. Accordingly, the December 31, 2020 and December 31, 2019 comparative statements of comprehensive income and loss and related notes have been re-presented retrospectively based on the accounting policies as outlined in note 3.4.4.

The accompanying notes form an integral part of these consolidated financial statements.

Consolidated Statements of Cash Flows

Cash flow (used in) / from operating activities (In thousands of $)	NOTE	Year Ended December 31, 2021	Year Ended December 31, 2020(*)	Year Ended December 31, 2029(*)
Operating loss		**(348,746)**	**(477,617)**	**(198,892)**
Adjustments for non-cash items				
Amortization of intangible assets	5	776	246	43
Depreciation of property, plant and equipment	6	5,091	3,671	2,382
Provisions for employee benefits		260	76	64
Expense recognized in respect of share-based payments	14	179,366	96,932	44,236
Fair value gains on non-current financial assets at fair value through profit or loss		(11,152)	(2,951)	(1,214)
Non-cash revenue	7	(75,000)	—	—
		(249,405)	**(379,643)**	**(153,381)**
Movements in current assets/liabilities				
(Increase)/decrease in trade and other receivables	10	(31,632)	21,961	(25,709)
(Increase)/decrease in inventories	9	(83,880)	(23,852)	—
(Increase)/decrease in other current assets		(30,990)	(16,189)	(5,788)
Increase/(decrease) in trade and other payables	15	134,892	50,537	53,729
Increase/(decrease) in deferred revenue – current	16	(46,327)	(40,441)	69,526
Movements in non-current assets/liabilities				
(Increase)/decrease in other non-current assets		(13,975)	(10,299)	(6,224)
Increase/(decrease) in deferred revenue – non-current	16	(269,039)	2,655	224,492
Cash flows (used in)/from operating activities		**(590,356)**	**(395,272)**	**156,645**
Interest paid		(684)	(401)	(139)
Income taxes paid		(15,772)	(2,791)	(4,876)
Net cash flow (used in) / from operating activities		**(606,812)**	**(398,463)**	**151,630**
Purchase of intangible assets	5	(117,811)	(4,071)	(44,939)
Purchase of property, plant and equipment	6	(3,623)	(1,068)	(1,796)
(Increase)/decrease in financial assets – current	11	(228,239)	341,869	(792,655)
Interest received		2,603	7,962	6,122
Net cash flow (used in) / from investing activities		**(347,070)**	**344,692**	**(833,267)**
Principal elements of lease payments	22	(3,855)	(2,550)	(1,515)
Proceeds from issue of new shares	13	1,091,326	813,186	755,641
Issue costs paid	13	(528)	(613)	(25,747)
Exchange gain from currency conversion on proceeds from issue of new shares		966	68	—
Proceeds from exercise of stock options	13	33,433	22,912	5,345
Net cash flow (used in) / from financing activities		**1,121,342**	**833,003**	**733,726**
Net increase (decrease) in cash & cash equivalents		**167,460**	**779,232**	**52,088**
Cash and cash equivalents at the beginning of the period		**1,216,803**	**372,162**	**321,791**
Exchange gains/(losses) on cash & cash equivalents		(49,587)	65,409	(1,717)
Cash and cash equivalents at the end of the period		**1,334,676**	**1,216,803**	**372,162**

* The Company has adopted a change in its presentation currency from EUR to USD at January 1, 2021, as described in note 3.4.4. Accordingly, the December 31, 2020 and December 31, 2019 comparative statements of profit and loss and related notes have been re-presented retrospectively based on the accounting policies as outlined in note 3.4.4.

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	Other reserves	Total equity attributable to owners of the parent	**Total equity**
Balance at January 1, 2019	**4,451**	**796,894**	**(202,270)**	**(18,954)**	**36,341**	**616,462**	**616,462**
Loss for the year			(181,208)			(181,208)	(181,208)
Other comprehensive income / (loss)				(8,587)		(8,587)	(8,587)
Total comprehensive loss of the period			**(181,208)**	**(8,587)**		**(189,795)**	**(189,795)**
Share-based payment					44,236	44,236	44,236
Issue of share capital	710	756,472				757,182	757,182
Transaction costs for equity issue		(25,476)				(25,476)	(25,476)
Accounting treatment of the share subscription agreement		(27,635)				(27,635)	(27,635)
Exercise of stock options	48	5,386				5,434	5,434
Balance year ended December 31, 2019	**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 loss of the period			**(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 new shares	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 loss of the period			(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 new shares	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**	**333,729**	**2,534,224**	**2,534,224**

* The Company has adopted a change in its presentation currency from EUR to USD at January 1, 2021, as described in note 3.4.4. Accordingly, the December 31, 2020 and December 31, 2019 comparative statements of profit and loss and related notes have been re-presented retrospectively based on the accounting policies as outlined in note 3.4.4.

Please refer to note 13 for more information on the share capital and movement in number of shares. See also note 14 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 Willemstraat 5, 4811 AH, Breda, 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 Impacts of COVID-19 on Our Business

The current unprecedented challenges as a result of the COVID-19 outbreak have impacted how we operate. We have been taking, and continue to take, the necessary steps in terms of safety, risk mitigation, and financial measures to best manage through these challenging times. We have currently experienced limited impact on our financial performance and financial position, although we continue to face additional risks and challenges associated with the impact of the outbreak.

3 Significant Accounting Policies

The significant Company’s accounting policies are summarized below.

3.1 Statement of compliance and basis of preparation

The consolidated financial statements are prepared in accordance with the International Financial Reporting Standards (IFRS), issued by the International Accounting Standards Board (IASB) and the interpretations issued by the IASB’s International Financial Reporting Interpretation Committee. The consolidated financial statements provide a general overview of the Company’s activities and the results achieved. They present fairly 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 18, 2022.

3.2 Adoption of New and Revised Standards

New standards and interpretations applicable for the annual period beginning on January 1, 2021
New standards and interpretations for the annual period beginning on January 1, 2021 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, 2021
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.

3.3 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 inter-company 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.

3.4 Foreign Currency Transactions

3.4.1 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. As of January 1, 2021, the consolidated financial statements are presented in USD ($), which is the Company’s presentation currency.

3.4.2 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.

3.4.3 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 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 other comprehensive income.

3.4.4 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.

Comparison figures in the consolidated statements of financial position, the consolidated statements of profit or loss and the consolidated statements of other comprehensive income, the consolidated statements of changes in equity, consolidated statements of cash flows, and all disclosures have been re-presented, unless otherwise stated, using the procedures outlined below:

- Assets and liabilities are translated into USD at the closing rates applicable at the end of each reporting period.
- Income and expenses are translated at exchange rates at the dates of the respective transaction or average rates where these are a suitable proxy.
- Differences resulting from the re-presentation have been presented as translation difference, a component within shareholders' equity.
- Share capital, share premium, and other reserves are translated at historic rates prevailing at the date of transaction.

3.5 Intangible Assets

3.5.1 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.

3.5.2 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 Priority Review Voucher ("PRV") acquired in 2020 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 measured at cost and reviewed for impairment when events or circumstances indicate that the carrying value may not be recoverable. At the time the Company commits using the PRV to accelerate the review of a drug application, the intangible asset will be amortized and derecognized upon filing of the related Biologic License Application.

3.5.3. 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.

3.5.4 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.

3.6 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 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.

3.7 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.

3.8 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”.

3.9 Impairment of Assets

3.9.1 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.

3.9.2 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 statement of profit or loss and the statement 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 profit or loss.

3.10 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, 2021.

3.10.1 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 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 derecognized 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 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.

3.10.1.1 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 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 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.

3.10.1.2 Current financial assets at fair value through profit or loss

Current financial assets include financial assets measured at fair value through profit or loss and comprise of money market funds and term accounts that have an initial maturity equal or less than 12 months, but exceeding 3 months.

3.10.1.3 Cash equivalents measured at fair value through profit or loss

Cash equivalents measured at fair value through profit or loss may comprise of term accounts that have an initial maturity of equal or less than 3 months and 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

3.10.1.4 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.

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.

3.10.1.5 Cash

Cash are financial assets measured at amortized cost and comprise of cash balances and savings accounts.

3.10.1.6 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”.

3.10.1.7 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.

3.10.2 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 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.

3.11 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, 2021, no profits were available for distribution.

3.12 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.

3.13 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.

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.

3.14 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.

3.15 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 statement of profit and loss and statement 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 no longer 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.

3.16 Revenue and other operating income recognition

3.16.1 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.

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 its current collaboration and license agreements, the Company is mainly licensing its 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 the agreement, 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 other material collaboration and license agreements, the Company has 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 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 assess 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 recognized revenue at point in time for transfer of license and the Company recognizes revenue over time for supply of clinical and commercial products as 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.

3.16.2 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 and the consolidated statements of other comprehensive income, 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 and the consolidated statements of other comprehensive income, under the line "Other operating income".

3.17 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.

4. Critical Accounting Judgements and Key Sources of Estimation Uncertainty

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.

The following areas are areas where key assumptions concerning the future, and other key sources of estimation uncertainty at the end of the reporting period, have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year.

Critical estimates in applying accounting policies

Research and development cost accruals

The Company recognizes costs of $163.7 million, as specified in note 15 to the financial statements, incurred for clinical trial activities and manufacturing of drug products, as research and development expenses based on an evaluation of its vendors' progress toward completion of specific tasks. Timing of payment may differ significantly from the period in which the costs are recognized as expense, resulting in clinical trial accruals recognized within "Trade and other payables" in the consolidated statements of financial position.

Quantification of the research progress and the translation of the progress to these accruals requires estimates, because the progress is not directly observable. In estimating the vendors' progress toward completion of specific tasks, the Company therefore uses non-financial data such as patient enrollment, clinical site activations and vendor information of actual costs incurred. This data is obtained through reports from or discussions with Company personnel and outside service providers as to the progress or state of completion of trials, or the completion of services. Costs are expensed over the service period the services are provided. Costs for services provided that have not yet been paid are recognized as accrued expenses.

5 Intangible assets

(In thousands of $)	Acquired In-Process R&D	Software & databases	Other Intangibles	Total
Cost				
On January 1, 2019	**—**	**182**	**—**	**182**
Additions	45,000	293	—	45,293
Translation differences	(198)	(2)	—	(200)
On December 31, 2019	**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**
Amortization and impairment				
On January 1, 2019	**—**	**(118)**	**—**	**(118)**
Amortization	—	(43)	—	(43)
Translation differences	—	4	—	4
On December 31, 2019	**—**	**(158)**	**—**	**(158)**
Amortization	—	(246)	—	(246)
Translation differences	—	(33)	—	(33)
On December 31, 2020	**—**	**(437)**	**—**	**(437)**
Amortization	—	(470)	—	(470)
On December 31, 2021	**—**	**(907)**	**—**	**(907)**
Carrying Amount				
On December 31, 2019	44,802	315	—	45,117
On December 31, 2020	65,180	3,106	99,058	167,344
On December 31, 2021	70,180	2,446	99,058	171,684

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.

As of December 31, 2021, there are no 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 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[1]	Total
Cost						
On January 1, 2019	**3,105**	**—**	**—**	**—**	**290**	**3,395**
Adoption of IFRS 16	—	2,677	517	—	—	3,194
Additions	856	5,097	588	905	32	7,478
Translation differences	(55)	(33)	(7)	3	(5)	(97)
On December 31, 2019	**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**
Depreciation and impairment						
On January 1, 2019	**(2,439)**	**—**	**—**	**—**	**(13)**	**(2,452)**
Depreciation	(515)	(1,472)	(261)	(103)	(31)	(2,382)
Translation differences	45	(5)	(1)	—	—	39
On December 31, 2019	**(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
On December 31, 2021	**(4,565)**	**(6,774)**	**(1,411)**	**(1,093)**	**(116)**	**(13,958)**
Carrying Amount						
On December 31, 2019	997	6,264	836	805	273	9,175
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

1. The Company has elected not to reassess whether a contract is, or contains, a lease at the date of initial application. Instead, for contracts entered into before the transition date, the Company relied on its assessment made applying IAS 17 and IFRIC 4 Determining whether an Arrangement contains a Lease.

There are no commitments to acquire property, plant and equipment. Furthermore, no items of property, plant and equipment are pledged. See note 22 for information for leases where the Company is a lessee.

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.

(In thousands of $)	At December 31, 2021	At December 31, 2020	At December 31, 2019
Restricted Cash - non-current	1,707	1,509	708
Non-current financial assets held at fair value through profit or loss	17,459	6,307	2,916
Non-current financial assets held at fair value through OCI	35,710	—	—
Total other non-current assets	**54,876**	**7,816**	**3,624**

Non-current restricted cash on December 31, 2021 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.

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.

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 (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 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, 2021, 2020 and 2019.

(In thousands of $)	At December 31, 2021	At December 31, 2020	At December 31, 2019
Cost at January 1	**1,659**	**1,659**	**—**
Additions of the year	75,000	—	1,659
Cost at December 31	**76,659**	**1,659**	**1,659**
Fair value adjustments at January 1	**4,648**	**1,257**	**—**
Fair value adjustment of the year through profit or loss	11,152	2,951	1,214
Fair value adjustment of the year through OCI	(39,290)	—	—
Translation difference	—	440	43
Fair value adjustment at December 31	**(23,490)**	**4,648**	**1,257**
Net book value at December 31	**53,169**	**6,307**	**2,916**

8 Deferred Taxes

The amount of deferred tax assets and liability by type of temporary difference can be detailed as follows:

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
Profit in inventory	—	—	—
Property, plant and equipment	—	(167)	(167)
Intangible assets	—	(1,792)	(1,792)
Non-current fixed assets	—	—	—
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, 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)**

9 Inventories

(In thousands of $)	At December 31, 2021	At December 31, 2020	At December 31, 2019
Raw materials and consumables	70,134	18,608	—
Inventories in process	37,705	6,587	—
Finished goods	1,237	—	—
Total inventories	**109,076**	25,195	—

On December 31, 2021, inventories amounted to $109.1 million related to efgartigimod. Of the total inventory, $48.8 million relates to inventory which is currently awaiting facility approval. As of December 31, 2021, 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.

10 Trade and Other Receivables

The trade and other receivables are composed of receivables which are detailed below:

(In thousands of $)	At December 31, 2021	At December 31, 2020	At December 31, 2019
Trade receivable	28,058	287	25,367
Interest receivable	1,325	993	2,338
Other receivable	8,838	5,698	3,880
Total trade and other receivables	**38,221**	**6,978**	**31,585**

The carrying amounts of trade and other receivables approximate their respective fair values. On December 31, 2021, we did not have any provision for expected credit losses.

Please also refer to note 26 for more information on the financial risk management.

11 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.

(In thousands of $)	At December 31, 2021	At December 31, 2020	At December 31, 2019
Money market funds	73,052	130,290	804,099
Term accounts	929,000	649,359	324,400
Total current financial assets	**1,002,052**	**779,649**	**1,128,499**

On December 31, 2021, the current financial assets included €60.7 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.

12 Cash and Cash Equivalents

(In thousands of $)	At December 31, 2021	At December 31, 2020	At December 31, 2019
Money market funds	997,092	858,291	—
Term accounts	95,090	61,356	255,631
Cash and bank balances	242,494	297,156	116,531
Total cash and cash equivalents	**1,334,676**	1,216,803	372,162

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.

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, 2021, the cash and cash equivalents included €462.0 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.

13 Share Capital and Share Premium

On December 31, 2021, the Company's share capital was represented by 51,668,315 shares. All shares were issued, fully paid up and of the same class. The table below summarizes our capital increases, as a result of offerings and the exercise of stock options under the Company's Employee Stock Option Plan.

Roll forward of number of shares outstanding:

Number of shares outstanding on January 1, 2019	**35,975,312**
Exercise of stock options	419,317
Share subscription from Johnson & Johnson Innovation Inc.	1,766,899
Global public offering on Euronext and Nasdaq on November 7, 2019	4,000,000
Over-allotment option exercised by underwriters on November 8, 2019	600,000
Number of shares outstanding on December 31, 2019	**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**

On February 2, 2021, argenx SE offered 3,125,000 of its ordinary shares through a global offering which consisted of 1,608,000 ADSs in the U.S. at a price of $320.0 per ADS, before underwriting discounts and commissions and offering expenses; and 1,517,000 ordinary shares in the European Economic Area at a price of €265.69 per share, before underwriting discounts and commissions and offering expenses. On February 4, 2021, the underwriters of the offering exercised their over-allotment option to purchase 468,750 additional ADSs in full. As a result, argenx SE received $1,146.7 million in gross proceeds from this offering, decreased by $56.6 million of underwriter discounts and commissions, and offering expenses, of which $56.0 million has been deducted from equity. The total net cash proceeds from the offering amounted to $1,090.1 million.

On May 11, 2021 at the annual general meeting, the shareholders of the Company approved the authorization to the Board to issue a maximum of 10% of the then-outstanding share capital for a period of 18 months.

On December 31, 2021, an amount of €410,857.7, represented by 4,108,577 shares, still remained available under the authorized capital.

14 Share-based Payments

Stock Option Plans
The Company has a stock options scheme for the employees of the Company and its subsidiaries. In accordance with the terms of the plan, as approved by shareholders, employees may be granted stock options to purchase ordinary shares at an exercise price as mentioned below per ordinary share.

The stock options are granted to employees, consultants or directors of the Company and its subsidiaries. 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, 2021, the economic benefits of 190,560 stock options, for which accelerated vesting applies, were transferred to a third party.

No other conditions are attached to the stock options.

The following share-based payment arrangements were in existence during the current and prior years and which are exercisable at the end of each period presented:

Expiry date	Exercise price per stock options (in $)[1]	Outstanding stock options on December 31, 2021	Outstanding stock options on December 31, 2020	Outstanding stock options on December 31, 2019
2020	4.47	—	—	7,210
2022	2.76	125,339	—	—
2023	2.76	—	165,693	211,769
2024	2.76	94,088	100,086	102,696
2024	4.47	6,113	6,238	6,238
2024	8.12	276,500	294,167	335,067
2025	12.96	4,500	21,500	39,000
2025	11.71	—	950	3,000
2025	10.73	105,857	114,232	185,832
2026	12.89	41,000	45,000	45,000
2026	12.99	102,840	127,252	219,791
2026	16.00	117,581	176,426	258,746
2027	20.85	53,143	102,479	108,613
2027	23.98	361,350	460,701	565,798
2023	91.54	85,080	85,077	94,100
2028	91.54	39,515	49,532	73,100
2023	97.77	321,473	325,661	366,260
2028	97.77	350,631	381,317	402,714
2024	128.54	111,174	111,174	111,690
2029	128.54	146,765	163,410	299,560
2024	153.75	203,658	195,452	204,430
2029	153.75	611,122	692,914	717,455
2025	135.38	16,712	19,000	—
2030	135.38	102,558	123,700	—
2025	222.16	129,711	131,770	—
2030	222.16	282,475	325,150	—
2025	226.77	32,100	32,100	—
2030	226.77	136,601	175,200	—
2030	280.43	692,214	728,517	—
2025	280.43	203,214	211,045	—
2026	265.48	24,366	—	—
2026	288.93	61,505	—	—
2026	293.91	48,138	—	—
2031	265.48	42,282	—	—
2031	288.93	207,464	—	—
2031	293.91	92,456	—	—
2026/2031 [2]	350.20	389,588	—	—
		5,619,113	**5,365,743**	**4,358,069**

(1) Amounts have been converted to USD at the closing rate as of December 31, 2021.
(2) As of December 2021, the Company granted options for which the beneficiaries had a 60-day period to choose between a contractual term of five or ten years

	2021		2020		2019	
	Number of stock options	Weighted average exercise price(*)	Number of stock options	Weighted average exercise price(*)	Number of stock options	Weighted average exercise price(*)
Outstanding at January 1	**5,365,743**	**142.87**	**4,358,069**	**78.23**	**3,536,651**	**37.54**
Granted	882,584	314.99	1,797,652	266.71	1,365,172	144.38
Exercised	(503,282)	64.72	(602,463)	38.86	(419,317)	12.75
Forfeited	(125,932)	234.98	(187,515)	170.98	(124,437)	99.89
Outstanding at December 31	**5,619,113**	**164.33**	**5,365,743**	**142.87**	**4,358,069**	**71.62**
Exercisable at December 31	**3,613,371**	**106.53**	**2,833,680**	**65.24**	**2,203,476**	**25.38**

* 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, 2021 was $305.9, compared to $254.54 during the year ended December 31, 2020 and $124.69 during the year ended December 31, 2019. The weighted average remaining contractual life of the stock options outstanding amounted to 6.3 years on December 31, 2021 compared to 7.08 years on December 31, 2020 and 7.27 years on December 31, 2019. The table below shows the weighted average remaining contractual life for each range of exercise price:

Exercise price (in $)	Outstanding on December 31, 2021	Weighted average remaining contractual life (in years)
2.76 - 4.47	225,540	1.50
8.12 - 10.73	382,357	3.24
11.71 - 16.00	265,921	4.64
20.85 - 23.98	414,493	5.90
91.54 - 97.77	796,699	4.35
128.54 - 153.75	1,191,989	6.50
222.16 - 280.43	1,542,963	7.56
288.93 - 350.20	799,151	9.10

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 2021:

Stock options granted in	April 2021	July 2021	October 2021	December 2021 (1)
Number of options granted	67,833	280,339	144,824	389,588
Average Fair value of options (in $) (*)	98.96 - 154.88	131.65 - 159.13	101.53 - 131.80	145.35 - 149.09
Share price (in $) (*)	248.9 - 283.67	300.78 - 340.95	286.52 - 304.5	351.73
Exercise price (in $) (*)	275.33	303.16	301.02	349.92
Expected volatility	54.24 - 60.08 %	45.58 - 47.96 %	46.01 - 48.46 %	43.57 - 43.58 %
Average Expected option life (in years)	4 - 6.50	4 - 6.50	4 - 6.50	6.15 - 6.50 (1)
Risk-free interest rate	(0.41) - (0.08) %	(0.41) - (0.17)	(0.18) - (0.05) %	0.03 - 0.05 %
Expected dividends	—	—	—	—

(1) In December 2021, the Company granted a total of 389,588 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 $45.0 million (100% of the stock options with a contractual term of five years) to $57.1 million (100% of the stock options with a contractual term of ten years).
(*) 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 2020:

Stock options granted in	April 2020	Juny 2020	October 2020	December 2020
Number of options granted	142,700	550,090	196,500	908,362
Average Fair value of options (in $) (*)	76.46 - 148.03	83.46 - 129.64	91.10 - 156.68	101.23 - 229.20
Share price (in $) (*)	155.23 - 252.29	224.80 - 281.25	256.46 - 293.52	273.15 - 383.10
Exercise price (in $) (*)	146.68	240.70	245.69	303,83
Expected volatility	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	(0.32) - (0.18) %	(0.43) - (0.28) %	(0.51) - (0.34) %	(0.51) - (0.28) %
Expected dividends	—	—	—	—

(*) amounts have been converted to USD at the closing rate of the respective period.

Below is an overview of the parameter used in relation to the determination of the fair value of grants during 2019:

Stock options granted in	June 2019	November 2019	December 2019
Number of options granted	423,487	19,800	921,885
Average Fair value of options (in $) (*)	71.28	64.81	46.51 - 74.58
Share price (in $) (*)	138.40	142.00	146.15-169.30
Exercise price (in $) (*)	127.49	127.49	152.50
Expected volatility	45.25 %	44.14 %	43.80 - 44.11 %
Average expected option life (in years)	8.59	6.50	4 - 6.5
Risk-free interest rate	0.07 %	(0.05) %	(0.57) - (0.24) %
Expected dividends	—	—	—

(*) amounts have been converted to USD at the closing rate of the respective period.

The total share-based payment expense recognized in the consolidated statements of comprehensive income totaled $179.4 million for the year ended December 31, 2021, compared to $96.9 million for the year ended December 31, 2020 and $44.2 million for the year ended December 31, 2019.

15 Trade and Other Payables

(In thousands of $)	At December 31, 2021	At December 31, 2020	At December 31, 2019
Trade payables	208,850	206,325	65,639
Short-term employee benefits	83,737	68,867	30,188
Other	828	—	—
Total trade and other payables	**293,415**	**275,192**	**95,827**

Trade payables correspond primarily to clinical and manufacturing activities and include accrued expenses related to these activities.

As of December 31, 2021 and December 31, 2020, the trade payables include accruals amounting to $163.7 million and $64.5 million, respectively, related to accruals from clinical manufacturing organizations for the manufacturing of drug products and from clinical research organisations.

Short-term employee benefits include payables and accruals for salaries and bonuses to be paid to the employees of the Company.

16 Revenue

The following table summarizes details of revenues for the year ended December 31, 2021, 2020 and 2019 by collaboration agreement and by category of revenue: upfront payments, milestone payments and research and development service fees.

(In thousands of $)	Year Ended December 31, 2021	Year Ended December 31, 2020	Year Ended December 31, 2019
Zai Lab	151,903	—	—
Janssen	292,279	33,759	22,386
AbbVie	121	565	855
Agomab	—	—	1,684
Other	—	38	50
Upfront payments	**444,303**	**34,362**	**24,975**
Zai Lab	25,634	—	—
Janssen	22,865	2,641	1,738
AbbVie	102	762	30,077
Other	1,214	19	25
Milestone payments	**49,815**	**3,422**	**31,840**
Janssen	2,028	3,175	21,236
Other	298	284	411
Research and development service fees	**2,326**	**3,459**	**21,647**
Zai Lab	833	—	—
Other revenues	**833**	**—**	**—**
Total revenue	**497,277**	**41,243**	**78,462**

For the years ended December 31, 2021, 2020 and 2019, the majority of the revenue was generated under the agreements with Zai Lab, Janssen and AbbVie, each as described below.

The table below summarizes the changes in deferred revenue – current and deferred revenue – non-current for the year ended December 31, 2021, 2020 and 2019.

(In thousands of $)	Janssen	AbbVie	Other	**Total**
On January 1, 2019	**—**	**2,342**	**133**	**2,475**
Received				
Upfront	328,327	—	—	328,327
Milestone	25,000	30,000	—	55,000
Revenue recognition				
Upfront	(22,386)	(855)	(50)	(23,291)
Milestone	(1,738)	(30,077)	(25)	(31,840)
Translation difference	(4,575)	107	(2)	(4,470)
On December 31, 2019	**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	**—**	**—**	**—**	**—**

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 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 currently 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 upon approval of efgartigimod in the U.S. and the consideration received in return for the supply of clinical and commercial product. 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 associated with the contingent consideration is subsequently resolved. We estimate the amount to be included in the transaction price upon achievement of the milestone event or 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 upon 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 recognised 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 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 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 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

(In thousands of $)	Year Ended December 31, 2021	Year Ended December 31, 2020	Year Ended December 31, 2019
Grants	4,398	1,365	2,563
Research and development incentives	13,970	10,257	5,373
Payroll tax rebates	12,621	9,095	6,413
Change in fair value on non-current financial assets	11,152	2,951	1,214
Total other operating income	**42,141**	**23,668**	**15,563**

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 receivable of $14.0 million in the year ended December 31, 2021, compared to $10.3 and $5.4 million in the year ended December 31, 2020 and December 31, 2019, 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 $12.6 million payroll tax rebates in the year ended December 31, 2021, compared to $9.1 and $6.4 million in the year ended December 31, 2020 and December 31, 2019, 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 and France. Revenues are generated by external customers with their main registered office geographically located as shown in the table below.

Revenue from external customers (In thousands of $)	Year Ended December 31, 2021	Year Ended December 31, 2020	Year Ended December 31, 2019(*)
Denmark	1,389	342	488
Belgium	—	—	1,684
United States	317,396	40,901	76,290
China	178,370	—	—
Other	123	—	—
Total	**497,277**	**41,243**	**78,462**

* In prior periods this has been presented based on the geographical location of the contracting entity.

The non-current assets of the Company, with the exception of the deferred tax assets, are geographically located as shown in the table below:

Non-current assets (In thousands of $)	At December 31, 2021	At December 31, 2020	At December 31, 2019(*)
Netherlands	—	1	1
Belgium	268,733	200,125	63,785
United States	3,138	4,751	3,435
Japan	3,232	2,491	319
Switzerland	8	—	—
Total	**275,111**	**207,368**	**67,540**

* In prior periods this has been presented based on the geographical location of the contracting entity.

19 Research and Development Expenses

(In thousands of $)	Year Ended December 31, 2021	Year Ended December 31, 2020	Year Ended December 31, 2019
Personnel expenses	160,464	86,036	51,172
External research and development expenses	382,902	259,943	152,889
Materials and consumables	2,735	3,562	2,267
Depreciation and amortization	3,742	2,835	1,840
Other expenses	30,677	18,509	12,603
Total research and development expenses	**580,520**	**370,885**	**220,771**

20 Selling, General and Administrative Expenses

(In thousands of $)	Year Ended December 31, 2021	Year Ended December 31, 2020	Year Ended December 31, 2019
Personnel expenses	164,646	108,507	44,774
Professional fees	102,674	48,681	18,181
Supervisory board	12,958	4,838	3,127
Other Expenses	27,366	9,617	6,064
Total Selling, general and administrative expenses	**307,644**	**171,643**	**72,146**

21 Personnel Expenses

The personnel expenses mentioned in note 19 and 20 above are as follows:

(In thousands of $)	Year Ended December 31, 2021	Year Ended December 31, 2020	Year Ended December 31, 2019
Short-term employee benefits—Salaries	135,676	75,437	36,747
Short-term employee benefits—Social Security	12,785	9,087	3,996
Post-employment benefits	2,864	1,242	837
Termination benefits	818	1,005	722
Share-based payment	167,965	92,558	41,612
Employer social security contributions stock options	5,002	15,214	12,032
Total personnel expenses	**325,110**	**194,543**	**95,946**

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 department is presented below:

Average Number of FTE	Year Ended December 31, 2021	Year Ended December 31, 2020	Year Ended ecember 31, 2019
Research and development	349.7	213.0	121.6
Selling, general and administrative	264.4	119.5	56.3
	614.1	**332.5**	**177.9**

22 Leases

The statement of financial position shows the following amounts relating to leases:

(In thousands of $)	Year Ended December 31, 2021	Year Ended December 31, 2020	Year Ended December 31, 2019
Right-of-use assets			
Buildings	9,688	7,677	6,264
Vehicles	1,664	1,513	836
Equipment	230	264	273
	11,583	**9,454**	**7,373**
Lease liabilities			
Current	3,509	3,476	2,218
Non-current	7,956	6,181	5,101
	11,465	**9,657**	**7,319**

Additions to the right-of-use assets amounted to $5.7 million for the year ended December 31, 2021.

The table below shows a maturity analysis of the lease liabilities as on December 31, 2021:

(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	3,509	6,331	2,164	—	12,004	11,465

The consolidated statements of profit or loss and the consolidated statements of other comprehensive income shows the following amounts relating to leases:

(In thousands of $)	Year Ended December 31, 2021	Year Ended December 31, 2020	Year Ended December 31, 2019
Depreciation charges			
Buildings	2,714	2,262	1,472
Vehicles	651	441	261
Equipment	34	32	31
	3,399	**2,735**	**1,764**
Interest expense (included in finance cost)	412	201	117
Expense relating to short-term leases	212	264	137
Expense relating to leases of low-value assets that are not shown above as short-term leases	7	6	6

The total cash outflow for leases in 2021 and 2020 was $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)

(In thousands of $)	Year Ended December 31, 2021	Year Ended December 31, 2020	Year Ended December 31, 2019
Interest income	3,489	5,119	8,805
Net gain on current financial assets held at fair value through profit or loss and cash equivalents	144	1,340	7,317
Financial income	**3,633**	**6,459**	**16,122**
Net loss on current financial assets held at fair value through profit or loss and cash equivalents	(3,482)	(7,559)	—
Other financial expense	(1,096)	(401)	(139)
Financial expense	**(4,578)**	**(7,960)**	**(139)**
Realized exchange gains/(losses)	15	(443)	(385)
Unrealized exchange gains/(losses)	(50,068)	(125,791)	7,375
Exchange gains/(losses)	**(50,053)**	**(126,234)**	**6,990**

The exchange losses of $50.1 million for the year ended December 31, 2021 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 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:

(In thousands of $)	Year Ended December 31, 2021	Year Ended December 31, 2020	Year Ended December 31, 2019
Loss before taxes	399,743	605,352	175,919
Income tax calculated at 25%	99,936	151,338	43,980
Effect of expenses and gains that are not deductible in determining taxable results	(34,366)	(12,813)	(8,625)
Effect of stock issue expenses that are not deductible in determining taxable results	14,119	14,139	6,363
Effect of concessions	13,413	7,900	635
Effect of tax losses carried forward not recognized	(44,232)	(116,711)	(12,952)
Effect of different tax rates in jurisdictions in which the company operates	(2,084)	(195)	(58)
Deferred tax asset other than loss carryforwards not recognized	(50,389)	(45,601)	(30,336)
Withholding tax paid	(5,076)	—	—
(Underprovided)/overprovided in prior years	398	(1,014)	(4,310)
Other	(241)	(146)	15
Income tax expense recognized in the consolidated statements of profit or loss	**(8,522)**	**(3,103)**	**(5,289)**

The tax rate used for the 2021, 2020 and 2019 reconciliations above is the corporate income tax rate of 25% payable by corporate entities in the Netherlands.

The unrecognized deferred tax asset on unused tax losses amounts to $203.8 million on December 31, 2021, compared to $174.2 million on December 31, 2020. Deferred tax have been measured using the effective rate that will apply in Belgium and the Netherlands (25%). The Company has unused tax losses carried forward for an amount of $815.3 million on December 31, 2021, compared to $696.7 million on December 31, 2020. This, combined with other temporary differences, resulted in a net deferred tax asset position. 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 8.

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 2021 and 2020, we had $161.5 million and $52.1 million of carry-forward IID in Belgium.

Income taxes were directly recognized in the income statement can be detailed as follows:

(In thousands of $)	Year Ended December 31, 2021	Year Ended December 31, 2020	Year Ended December 31, 2019
Current year	15,224	7,847	5,289
Income tax prior years	(398)	1,732	—
Current tax expense	**14,826**	**9,579**	**5,289**
Originating and reversal of temporary differences	(6,304)	(6,476)	—
Deferred tax expense / (income)	**(6,304)**	**(6,476)**	**—**
Total tax expense	**8,522**	**3,103**	**5,289**

25 Loss per Share

(In thousands of $)	Year Ended December 31, 2021	Year Ended December 31, 2020	Year Ended December 31, 2019
Loss of the year	(408,265)	(608,455)	(181,208)
Weighted average number of shares outstanding	51,075,827	45,410,442	38,619,121
Basic and diluted loss per share (in $)	**(7.99)**	**(13.40)**	**(4.69)**

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 2021, 2020 and 2019, stock options have an anti dilutive effect rather than a dilutive effect. As such, there is no difference between basic and diluted earnings/losses 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		
(In thousands of $)		At December 31, 2021	At December 31, 2020(*)	At December 31, 2019(*)
Financial assets — non-current	FVTPL	17,459	6,307	2,916
Financial assets — non-current	FVTOCI	35,710	—	—
Research and development incentive receivables — non-current	Amortised cost	32,707	20,626	9,624
Restricted cash — non-current	Amortised cost	1,707	1,509	708
Trade and other receivables	Amortised cost	38,221	6,978	31,585
Financial assets—current	FVTPL	73,052	130,290	804,099
Financial assets—current	Amortised cost	929,000	649,359	324,400
Research and development incentive receivables — current	Amortised cost	—	463	293
Cash and bank balances	Amortised cost	242,494	297,156	116,531
Cash equivalents	FVTPL	997,092	858,291	—
Cash equivalents	Amortised cost	95,090	61,356	255,631
Trade and other payables	Amortised cost	293,415	275,192	95,827

* The historical consolidated financial information for 2020 and 2019 presented in this disclosure note has been adjusted to present the breakdown of current financial assets that are measured at FVTPL and amortized cost.

* The historical consolidated financial information for 2020 and 2019 presented in this disclosure note has been adjusted to present the breakdown of current

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, 2021, 2020 and 2019 respectively:

	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 Equivalents	997,092	—	—
Assets carried at fair value	**1,105,854**	**—**	**17,459**

	At December 31, 2020(*)		
(In thousands of $)	Level 1	Level 2	Level 3
Non-current financial assets	—	—	6,307
Current financial assets	130,290	—	—
Cash Equivalents	858,291	—	—
Assets carried at fair value	**988,581**	**—**	**6,307**

* 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.

	At December 31, 2019(*)		
(In thousands of $)	Level 1	Level 2	Level 3
Non-current financial assets	—	—	2,916
Current financial assets	804,099	—	—
Assets carried at fair value	**804,099**	**—**	**2,916**

* The historical consolidated financial information for 2019 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.

Non-current financial assets – Level 1
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, 2021, cash and cash equivalents amounted to $1,334.7 million and total capital amounted to $3,469 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 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, 2021, if applicable interest rates would increase/decrease by 25 basis points, this would have a positive/negative impact of $0.9 million (compared to $1.7 million for the year ended December 31, 2020 and $2.2 million for the year ended December 31, 2019).

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:

(In thousands of $)	At December 31, 2021	At December 31, 2020	At December 31, 2019
EUR	591,887	703,016	578,483
JPY	6,316	264	856
GBP	1,237	48	4
CHF	727	2	1

On December 31, 2021, if the EUR/USD exchange rate would have increased/decreased by 10%, this would have had a negative/positive impact of $53.81million, compared to $63.91 million and $52.6 million on December 31, 2020 and December 31, 2019, respectively. On December 31, 2021, 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 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.

27.2 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, 2021, 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, 2021, the board of directors consisted of 8 members: Peter Verhaeghe, Don deBethizy, Pamela M. Klein, Werner Lanthaler, A.A. Rosenberg, James M. Daly, Yvonne Greenstreet 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:

(In thousands of $, except for the number of stock options & RSUs)	Year Ended December 31, 2021	Year Ended December 31, 2020	Year Ended December 31, 2019
Remuneration of key management personnel			
Short-term benefits for senior management members as a group			
Gross salary	3,465	3,246	2,829
Variable pay	2,020	1,510	1,091
Employer social security	789	753	910
Other short term benefits	274	156	137
Termination Benefits	382	385	526
Post-employment benefits for senior management members as a group	150	161	161
Cost of stock options granted in the year for senior management members as a group	15,060	42,824	24,457
Cost of restricted stock units granted in the year for senior management members as a group	8,025	—	—
Employer social security cost related to stock options	4,172	11,206	10,255
Total benefits for key management personnel	**34,337**	**60,241**	**40,366**
Numbers of stock options granted in the year			
Senior Management as a group	101,446	334,900	405,000
Numbers of restricted stock units granted in the year			
Senior Management as a group	22,888	—	—
Remuneration of non-executive directors			
Board fees and other short-term benefits for non-executive directors	435	405	423
Cost of stock options granted in the year for non-executive directors	3,263	9,576	4,847
Cost of restricted stock units granted in the year for non-executive directors	1,731	—	—
Total benefits for non-executive board members	**5,429**	**9,981**	**5,270**
Numbers of stock options granted in the year			
Non-executive directors	22,950	70,000	70,000
Numbers of restricted stock units granted in the year			
Non-executive directors	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 executive team. 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 executive team 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	—	—	1,437	17,718	19,155

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 commercialisation. 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 $312.4 million.

30 Audit fees

The following auditors' fees were expensed in the income statement:

(In thousands of $)	Year Ended December 31, 2021	Year Ended December 31, 2020	Year Ended December 31, 2019
Audit Fees [1]	1,183	923	817
Audit-related Fees	267	188	178
Tax Fees [2]	79	—	—
All other Fees	—	—	—
Total	**1,529**	**1,111**	**995**

(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 and other 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 IIP BV, based in Belgium. argenx BV has five subsidiary, argenx US, Inc., based in the United States of America, argenx Japan KK, based in Japan, argenx Switzerland SA, based in Switzerland, argenx France SAS based in France and argenx Germany GmbH based in Germany. Details of the Company's consolidated entities at the end of the reporting period are as follows:

Name	Registration number	Country	Participation	Main activity
argenx SE	COC 24435214	The Netherlands	100.00 %	Holding company
argenx BV	0818292196	Belgium	100.00 %	Biotechnical research on drugs and pharma processes
argenx IIP BV	0751809485	Belgium	100.00 %	Biotechnical research on drugs and pharma processes
argenx US, Inc.	36-4880497	USA	100.00 %	Pharmaceuticals and pharmacy supplies merchant wholesalers
argenx Switzerland, SA	CH-660.3.799.020-7	Switzerland	100.00 %	Pharmaceuticals and pharmacy supplies merchant wholesalers
argenx Japan KK	0104-01-145183	Japan	100.00 %	Pharmaceuticals and pharmacy supplies merchant wholesalers
argenx France SAS	90065093800013	France	100.00 %	Pharmaceuticals and pharmacy supplies merchant wholesalers
argenx Germany GmbH	HRB 268437	Germany	100.00 %	Pharmaceuticals and pharmacy supplies merchant wholesalers

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.

Company Financial Statements

FOR ARGENX SE - FOR THE YEAR ENDED DECEMBER 31, 2021

Contents

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 18, 2022.

Company Financial Statements for argenx SE

For argenx SE
For the year ended December 31, 2021

Company Balance Sheet on December 31, 2021 argenx SE

Assets (In thousands of $)	NOTE	At December 31, 2021	At December 31, 2020(*)
Non-current Assets			
Financial Fixed Assets	2		
Investments in Group Companies		2,412,741	1,536,080
Other financial assets		1	1
Total Financial Fixed assets		**2,412,742**	**1,536,081**
Total Non-Current Assets		**2,412,742**	**1,536,081**
Current assets			
Receivables	3	1,993	6,155
Financial assets — current	4	4,985	5,430
Cash in banks	5	142,853	117,995
Total Current Assets		**149,831**	**129,579**
Total Assets		**2,562,573**	**1,665,661**

Equity and liabilities (In thousands of $)	NOTE	At December 31, 2021	At December 31, 2020(*)
Equity	**6**		
Share Capital		6,233	5,744
Share Premium		3,462,775	2,339,033
Accumulated losses		(1,400,196)	(991,931)
Reserve for Share-Based payments		356,875	177,509
Translation reserves		134,041	134,041
Total Equity		**2,559,728**	**1,664,396**
Current liabilities	7		
Accounts Payable		70	0
Intercompany payables		1,232	655
Taxes payable		95	0
Accrued expenses		620	610
Other payables		827	0
Total Liabilities		**2,845**	**1,265**
Total Equity & Liabilities		**2,562,573**	**1,665,661**

* The Company has adopted a change in its presentation currency from EUR to USD at January 1, 2021, as described in note 1.3. Accordingly, the December 31, 2020 comparative statements and related notes have been re-presented retrospectively based on the accounting policies as outlined in note 1.3.

Company Profit or Loss Account for the Year Ended December 31, 2021 argenx SE

(In thousands of $)	NOTE	Year ended December 31, 2021	Year ended December 31, 2020(*)
Intercompany Recharges		—	—
Total operating income		**—**	**—**
G&A Expenses		(21,944)	(12,738)
Total operating expenses		**(21,944)**	**(12,738)**
Operating result		**(21,944)**	**(12,738)**
Financial income and expense	8	(5,231)	(1,626)
Share in result of subsidiaries	9	(381,493)	(589,668)
Result before taxation		**(408,668)**	**(604,032)**
Taxation on result of ordinary activities		404	(101)
Result after taxation		**(408,265)**	**(604,134)**

* The Company has adopted a change in its presentation currency from EUR to USD at January 1, 2021, as described in note 1.3. Accordingly, the December 31, 2020 comparative statements and related notes have been re-presented retrospectively based on the accounting policies as outlined in note 1.3.

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 100.107A, 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 reflects 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.

Comparison figures in the balance Sheet, profit or loss, and all disclosures have been re-presented, unless otherwise stated, using the procedures outlined below:

- Assets and liabilities are translated into USD at the closing rates applicable at the end of each reporting period.
- Income and expenses are translated at exchange rates at the dates of the respective transaction or average rates where these are a suitable proxy.
- Differences resulting from the re-presentation have been presented as translation difference, a component within shareholders' equity.
- Share capital, share premium, and other reserves are translated at historic rates prevailing at the date of transaction.

2. Financial Fixed Assets

The Company has two Belgian subsidiaries, argenx BV and argenx IIP BV, which carry out the research and development activities of the Group. Argenx IIP BV was incorporated through a partial demerger of argenx BV in 2020. Argenx BV has five subsidiaries, argenx US Inc. (United States), argenx Japan KK (Japan), argenx Switzerland SA (Switzerland), argenx Germany GmbH and argenx France SAS. The financial fixed assets consist of the 100% participations in argenx BV and, argenx IIP BV, both registered at Industriepark 7, Zwijnaarde, Belgium.

The movement in financial fixed assets is as follows:

(In thousands of $)	At December 31, 2021	At December 31, 2020
Investments in Group Companies		
Opening Balance	1,535,060	1,113,192
Share of loss of investments	(437,968)	(589,668)
Share-based payment expenses of investments	167,965	91,049
Translation reserves	—	(37,064)
Capital increase argenx BV	1,146,687	896,195
Partial demerger argenx BV	—	(10,623)
Incorporation argenx IIP BV	—	10,623
Capital increase argenx IIP BV	—	61,355
Closing balance	**2,411,743**	**1,535,060**
Receivable/(payable) on Group companies	999	1,020
Investments in Group companies	**2,412,741**	**1,536,080**
Other financial assets		
Opening Balance	1	1
Balance as at year-end	**1**	**1**
Total financial fixed assets	**2,412,742**	**1,536,081**

3 Receivables

(In thousands of $)	At December 31, 2021	At December 31, 2020
Interest receivable	—	—
Other receivables	949	505
Prepaid expenses	1,044	5,650
Total Receivables	**1,993**	**6,155**

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

(In thousands of $)	At December 31, 2021	At December 31, 2020
Money market funds	4,985	5,430
Term account	—	—
Total Financial asssets	**4,985**	**5,430**

5 Cash and Cash Equivalents

(In thousands of $)	At December 31, 2021	At December 31, 2020
Term deposits	47,365	68,846
Current bank accounts	95,488	49,149
Total Cash in banks	**142,853**	**117,995**

6 Equity

(In thousands of $)	Share Capital	Share Premium	Retained Earnings	Other Reserves	Translation Reserves	Total Equity
Equity per 1 January 2021 in EUR	**4,757**	**2,058,122**	**(861,491)**	**154,977**	**—**	**1,356,365**
Equity per 1 january 2021 at closing rate USD/EUR 31 December 2021	5,837	2,525,522	(1,057,136)	190,173	—	1,664,396
Correction for historical rate	(93)	(186,488)	65,204	(12,664)	134,041	—
Equity per 1 January 2021 in USD	**5,744**	**2,339,033**	**(991,931)**	**177,509**	**134,041**	**1,664,396**
Result of the year	—	—	(408,265)	—	—	(408,265)
SPB result	—	—	—	179,366	—	179,366
Capital increase exercised stock options	59	32,906	—	—	—	32,965
Capital increase financing 2021	430	1,090,836	—	—	—	1,091,266
Equity per 31 December 2021 in USD	**6,233**	**3,462,775**	**(1,400,196)**	**356,875**	**134,041**	**2,559,728**

For the details on Share Based Payments we refer to note 14 of the consolidated IFRS financial statements.
The company holds no legal reserves as part of the equity.

7 Current Liabilities

(In thousands of $)	At December 31, 2021	At December 31, 2020
Accounts payable	70	—
Intercompany payables	1,232	655
Taxes payable	95	—
Accrued expenses	620	610
Other payables	827	—
Total Current Liabilities	**2,845**	**1,265**

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)

(In thousands of $)	Year ended December 31, 2021	Year ended December 31, 2020
Interest income on bank deposits	—	142
Net gains on investments at FVTPL	—	—
Fees collected from ADS holders	484	402
Interest on I/C current account	—	—
Financial income	**484**	**544**
Net losses on investments at FVTPL	(364)	(538)
Interest expense	(116)	(86)
Other financial expenses	(44)	(27)
Financial expenses	**(524)**	**(652)**
Exchange gains/(losses)	**(5,191)**	**(1,519)**
Financial income and expense	**(5,231)**	**(1,626)**

9 Share in Result of Subsidiaries

As of December 31, 2021, the Company had two Belgian subsidiaries, argenx BV and argenx IIP BV, which jointly carry out the research and development activities of the Group.

(In thousands of $)	Year ended December 31, 2021	Year ended December 31, 2020
argenx BV	(421,774)	(572,033)
argenx IIP BV	(16,195)	(17,635)
	(437,968)	**(589,668)**

10 Other Disclosures

CONTINGENT LIABILITIES
The contingent liabilities of the Company consist of a rental agreement for office space at DocWork Breda for an amount of KEUR 6 per annum. The lease can be terminated annually.

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
See note 27 of the notes to the consolidated IFRS financial statements.

INFORMATION RELATING TO EMPLOYEES
During the year 2021, the Company had an average of 0.2 FTE (2020: 0.2 FTE).

AUDITOR'S FEES
See note 30 of the notes to the consolidated IFRS financial statements.

PROPOSAL FOR APPROPRIATION OF THE RESULT
The Company reported a net loss of $408.3 million for the year ended on December 31, 2021. The Board of Directors proposes to carry forward the net loss of the year 2021 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 2021 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.

Breda, March 18, 2022
The Director
Tim Van Hauwermeiren, CEO

Other Information

Provision in the Articles of Association Governing the Appropriation of Results

1. 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.

2. 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.

3. Distribution of dividends on the shares shall be made in proportion to the nominal value of each share.

4. 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.

5. 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.

6. The distribution of profits shall be made after the adoption of the annual accounts, from which it appears that the same is permitted.

7. 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.

8. 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.

9. 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.

10. 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 of.

Report on the Audit of the Financial Statements for the year ended December 31, 2021 included in the Annual Report

Our opinion
We have audited the accompanying financial statements for the year ended December 31, 2021 of argenx SE, based in Breda, 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, 2021, and of its result and its cash flows for the year ended December 31, 2021 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, 2021, and of its result for the year ended December 31, 2021 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 at December 31, 2021.
2. The following statements for the year ended December 31, 2021: 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, 2021.
2. The company profit or loss account for the year ended December 31, 2021.
3. The notes comprising a summary of the 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.

Materiality
Based on our professional judgement we determined the materiality for the financial statements as a whole at USD 29,500,000. The materiality is based on 3.5% of operating expenses. 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 1,475,000, 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 these proceduresat 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 about the consolidated financial statements.

Audit approach fraud risks
In accordance with the Dutch Standards on Auditing, we are responsible for obtaining reasonable assurance that the financial statements taken as a whole are free from material misstatements, whether due to fraud or error.

Inherent to our responsibilities for the audit of the financial statements, there is an unavoidable risk that material misstatements go undetected, even though the audit is planned and performed in accordance with Dutch law. The risk of undetected material misstatements due to fraud is even higher, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control. Also, we are not responsible for the prevention and detection of fraud and non-compliance with all laws and regulations. Our audit procedures differ from a forensic or legal investigation, which often have a more in-depth character.

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. In obtaining our understanding we performed inquiries with management (Chief Executive Officer, Chief Operating Officer, Chief Financial Officer), those charged with governance and others within the company. 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 and whistle blower procedures. We evaluated the design and the implementation and 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.

Following these procedures, and the presumed risks under the prevailing audit standards, we considered fraud risks related to management override of controls, including evaluating whether there was evidence of bias by the Executive Board, the executive leadership team and other members of management, which may represent a risk of material misstatement due to fraud. Our audit procedures to respond to these fraud risks include, among others, an evaluation of relevant internal controls and supplementary substantive audit procedures, including detailed testing of journal entries, evaluating the accounting estimates for bias and review of the supporting documentation in relation to post-closing adjustments. Data analytics, including selection of journal entries based on risk-based characteristics, form part of our audit approach to address the identified fraud risks.

Additionally, we performed further procedures including, among others, the following:

- 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 evaluated whether the selection and application of accounting policies, particularly those related to subjective measurements, 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 4 of the financial statements.

Our procedures to address fraud risks did not result in a Key Audit Matter.

Audit approach compliance with laws and regulations
We assessed the laws and regulations relevant to the Company through discussion with the legal counsel, 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, the company 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 the company's business and the complexity of law or 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's ability to continue its business, or to avoid material penalties (e.g., with laws and regulations as SEC regulations, Dutch Stock exchange regulations, FDA regulations and EMA regulations to the extent material for the financial statements of the company) 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 the company as to whether the company 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
Our responsibilities, as well as the responsibilities of the management and the Board of Directors, related to going concern under the prevailing standards are outlined in the "Description of responsibilities regarding the financial statements" section below. In fulfilling our responsibilities, we performed procedures including evaluating management's assessment of the company's ability to continue as a going concern and considering the impact of financial, operational, and other conditions. Based on these procedures, we did not identify any reportable findings related to the entity's ability to continue as a going concern.

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.

These matters were addressed in the context of our audit of the financial statements as a whole and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

Trade and Other Payables – Research and development cost accruals — Refer to Note 15 to the financial statements

Description	Our response
The company recognizes costs of USD 163.7 million, as specified in Note 15 to the financial statements, incurred for clinical trial activities as research and development expenses based on evaluation of its vendors' progress toward completion of specific tasks. Payment timing may differ significantly from the period in which the costs are recognized as expense, resulting in research and development cost accruals recognized within Trade and Other Payables in the Statement of Financial Position. Determination of the research progress and the translation of the progress to the research and development cost accruals requires judgment, because such progress is not directly observable. In estimating the vendors' progress toward completion of specific tasks, the company therefore uses data such as patient enrollment, clinical site activations and vendor information of actual costs incurred. This data is obtained through reports from or discussions with company personnel and outside service providers as to the progress or state of completion of trials, or the completion of services. Costs are expensed over the service period the services are provided. Costs for services provided that have not yet been paid are recognized as accruals. We identified the research and development cost accruals as a critical audit matter due to the number of ongoing clinical trial activities and the subjectivity involved in estimating research and development cost accruals and as auditing the research and development cost accruals involves judgement in evaluating the progress of the research and development activities relative to the costs incurred.	Our audit procedures related to the research and development cost accruals included the following, among others: • We tested controls over the appropriateness of the recording of the research and development accruals reflecting the progress of the clinical trials, including the quarterly review meetings between the finance department and clinical research personnel. • We read selected research and collaboration agreements, as well as amendments thereto, to evaluate whether the progress of the clinical trials reflects all relevant contractual elements. • We considered publicly available information (such as press releases and investor presentations) and board of directors' materials regarding the status of clinical trial activities and evaluated this information to the judgements applied in recording the accruals. • For a selection of contracts, we compared the amount of accruals at the end of the prior period to current year activity and evaluated the accuracy of the company's estimation methodology • We performed confirmation procedures with vendors related to the progress of significant projects to test the research and development cost input calculations. • We made selections of specific amounts recognized as research and development expense as well as those recognized as accrued expenses and performed the following procedures: - Evaluated management's estimate of the vendor's progress based on inquiries with company clinical operations personnel. - Reconciled any available related statement of work, purchase order, or other supporting documentation to management's estimate (such as communications between the company and vendors).
	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 research and development cost accruals.

Revenue – Determination of appropriate accounting of the license and collaboration agreement — Refer to Note 16 to the financial statements

Description	Our response
The company recognized revenue of USD 178.4 million related to a license and collaboration agreement with Zai Lab Limited. Under the terms of the agreement, the company received USD 175 million in collaboration payments, consisting of an upfront payment and milestone payment. The upfront payment of USD 150 million is comprised of a USD 75 million upfront cash payment and a USD 75 million payment in the form of newly issued Zai Lab shares. The company has received an additional milestone payment of USD 25 million upon obtaining regulatory approval of efgartigimod by the FDA in the US. In addition, the company is eligible to receive tiered royalties based on annual net sales of efgartigimod in Greater China. The company's license and collaboration agreement has been determined as representing two distinct performance obligations, being the transfer of the license over efgartigimod and the at arms-length supply of clinical and commercial product to Zai Lab Limited. The upfront payment and milestone payment are allocated to the performance obligation related to the transfer of the license, whereas sales-based royalties and revenue generated from supplying Zai Lab Limited with drug product are allocated to the performance obligation related to the supply of product. The company concluded that the license has standalone value as of the effective date of the contract. Therefore, the revenue related to the transfer of the license has been recognized at a point in time upon fulfillment of the performance obligation, being the granting of the license to Zai Lab Limited. The milestone payment was considered constrained upon the effective date of the contract and was recognized at the point in time of obtaining the FDA approval of efgartigimod. Revenue from royalties and supply of drug product to Zai Lab Limited will be recognized upon fulfillment of the performance obligation related to the supply of drug product. Given the complexity involved in determining the appropriate accounting treatment in line with IFRS and the fact that it is the first time that the efgartigimod license is considered to have standalone value for the company, we identified the initial accounting treatment of the license and collaboration agreement with Zai Lab Limited as a critical audit matter.	Our audit procedures for the accounting of the collaboration and license agreement included the following, among others: • We tested the controls over the appropriateness of the accounting of the license and collaboration agreement, including the review by management of the appropriate accounting treatment. • We read the license and collaboration agreement and evaluated whether management's accounting position considered all relevant facts and terms included in the agreement. • We further evaluated management's accounting position paper and evaluated management's conclusions to determine whether they had appropriately considered and applied the guidance and interpretation within IFRS 15. • We have consulted with our financial reporting experts on the accounting treatment of the license and collaboration agreement. 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 accounting of the license and collaboration agreement.

Report on the other information included in the Annual Report

In addition to the financial statements and our auditor's report thereon, the annual report contains other information that consists of:

- The Business section.
- The Corporate Governance section, including the Remuneration Report.
- 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 the 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 the Management's Board'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 the other legal and regulatory requirements

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 Reporting Format (ESEF)
In the Commission Delegated Regulation (EU) 2019/815 of 17 December 2018 supplementing Directive 2004/109/EC of the European Parliament and of the Council with regard to regulatory technical standards on the specification of a single electronic reporting format is regulated that the Annual Report of the company has to be prepared in a single electronic reporting format ("ESEF"). The requirements to be met are set out in the aforementioned delegated regulation (these requirements are hereinafter referred to as: the RTS on ESEF).

In our opinion, the Annual Report made up in XHTML format, including the partly tagged Consolidated Financial Statements as included in the reporting package by the Company, has been prepared in all material respects in accordance 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 in a reporting package. Our responsibility is to obtain reasonable assurance for our conclusion whether the Annual Report in this reporting package, is in accordance with the requirements. We have taken into consideration what is stated in Alert 43. Our procedures included:

- Obtaining an understanding of the entity's financial reporting process, including the preparation of the reporting package;
- Obtaining the reporting package and performing validations to determine whether the reporting containing the Inline XBRL instance document and the XBRL extension taxonomy files have been prepared in accordance with the technical specifications; and
- Examining the information related to the Consolidated Financial Statements in the reporting package to determine whether all required tagging has been applied and whether they 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 skepticism 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.

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 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 21, 2022

Deloitte Accountants B.V.
P.J. Seegers

Initial for identification purposes:

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Information Incorporated by Reference

9 Information Incorporated by Reference

Our consolidated financial statements as of and for the financial years ended December 31, 2021, 2020 and 2019 (including the independent auditor's reports thereupon) have been incorporated by reference in this Universal Registration Document. We have incorporated certain documents into this Universal Registration Document by reference. The parts of the documents incorporated herein by reference to which no specific reference has been made are either not relevant for investors or are covered elsewhere in this Universal Registration Document.

The following table contains a cross-reference list to the relevant pages of our consolidated financial statements for the financial year ended December 31, 2021, which are incorporated by reference in this Universal Registration Document:

Consolidated statement of financial position	p. 250
Consolidated statement of profit or loss and other comprehensive income	p. 252
Consolidated statement of cash flows	p. 254
Consolidated statement of changes in equity	p. 255
Notes to the consolidated financial statements for the year 2021	p. 256

The following table contains a cross-reference list to the relevant pages of the financial statements of argenx SE for the financial year ended December 31, 2021, which are incorporated by reference in this Universal Registration Document:

Company balance sheet on December 31, 2021	p. 300
Company profit or loss account for the year ended December 31, 2021	p. 301
Notes to the financial statements	p. 302
Independent auditor's report on the financial statements	p. 308

The following table contains a cross-reference list to the relevant pages of our annual report 2020 on which can be found our consolidated financial statements for the financial year ended December 31, 2020, which are incorporated by reference in this Registration Document:

Consolidated statement of financial position	p. 250
Consolidated statement of profit or loss and other comprehensive income	p. 252
Consolidated statement of cash flows	p. 254
Consolidated statement of changes in equity	p. 255
Notes to the consolidated financial statements for the year 2020	p. 256

The following table contains a cross-reference list to the relevant pages of our annual report 2019 on which can be found our consolidated financial statements for the financial year ended December 31, 2019, which are incorporated by reference in this Registration Document:

Consolidated statement of financial position	p. 250
Consolidated statement of profit or loss and other comprehensive income	p. 252
Consolidated statement of cash flows	p. 254
Consolidated statement of changes in equity	p. 255
Notes to the consolidated financial statements for the year 2020	p. 256

The full text of the Articles of Association and an unofficial English translation thereof are incorporated by reference in this Registration Document. Any information not listed in the tables above but included in the document The full text of the Articles of Association and an unofficial English translation thereof are incorporated by reference in this Universal Registration Document.

Any information not listed in the tables above but included in the document incorporated by reference is given for information purpose only.

The documents incorporated by reference are available on our website (www.argenx.com), at the following locations:

Annual report 2019	https://www.argenx.com/sites/default/files/media-documents/argenx_Annual_Report_2019.pdf
Annual report 2020	https://www.argenx.com/sites/default/files/report/argenx_report_2020_March_30_2021.pdf
Annual report 2021	https://www.argenx.com/sites/default/files/report/argenx_report_2021_March_21_2022.pdf
Articles of association	https://www.argenx.com/sites/default/files/media-documents/argenx_SE_Articles_of_Association_Consolidated_Version-NL.pdf https://www.argenx.com/sites/default/files/media-documents/argenx_SE_Articles_of_Association_Consolidated_Translation-ENG.pdf
Remuneration Policy	https://www.argenx.com/sites/default/files/media-documents/argenx_remuneration_policy_final_approved_11_May_2021.pdf

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Glossary

Contents

Cross Reference Table for Annual Reporting Requirements

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 Registration Document.

SOURCE OF REQUIREMENT	Topic		Location
Article 2:391 DCC, RJ 400, RJ 405	Report on the company's activities	1	Shareholder Letter Presentation of the Group
	Corporate structure	5	General Description of the Company and its Share Capital
	Board of directors report	4	Corporate Governance
	Primary risks and uncertainties	2	Risk Factors
	Risk appetite & control	4.5	Risk Appetite & Control
	Analysis of financial condition and results	6	Operating and Financial Review
	Information on research and development activities	1.3 1.4 1.5	Our Products and Product Candidates Collaboration Agreements License Agreements – General
	Forward looking paragraph		Outlook 2022
	Compensation statements and remuneration report	4.4	Remuneration Report of the Remuneration and Nomination Committee
RJ 430	Key figures, ratios etc.	6	Operating and Financial Review
Article 2:392 DCC/RJ 410	Auditors opinion	8	Attached to the 2021 Financial Report included herein
	Articles of association on the distribution of profits	5.12	Articles of Association on Profits, distributions and losses
	List of subsidiaries	1.1.1	Group Structure
Decree on contents of board report (*besluit inhoud bestuursverslag*) Article 2:391 sub 5 DCC	Corporate governance code comply-or-explain	4.1	Dutch Corporate Governance Code, "Comply or Explain"
	Main elements of financial management & control systems in connection with the company's financial reporting	4.5.5	Financial Risks and Controls
	Functioning of the general meeting	5.4	General Meeting of Shareholders and Voting Rights
	Composition and functioning of the board of directors and its committees	4.2.3 4.2.4	Board of Directors Non-Executive Directors
Article 10 Decree Takeover Directive (*besluit overnamerichtlijn*), Article 2:391 sub 5 DCC	Capital structure	5	General Description of the Company and its Share Capital
	Principal shareholders	5.3	Share Classes and Principal Shareholders
	Particular shareholder rights and limitations thereof	5.4	General meetings of Shareholders and Voting Rights
	Procedure for appointment of board members	4.2	Management Structure
	Procedure for amending the articles of association	5.6	Amendment of Articles of Association
	Authority of the board of directors to issue or acquire shares	5.2.5 5.2.7	Issue of Shares Acquisition of Shares in argenx's Capital
	Material arrangements, to which the company is a party, in relation to a public offer	5.5	Anti-Takeover Provisions

RJ = Guidelines on Annual Reporting (*Richtlijnen voor de Jaarverslaggeving*)

Management Confirmations

With due regard to best practice principle 1.4.3 of the Dutch Corporate Governance Code, we confirm that:

(i) This Univeral Registration Document provides sufficient insights into any failings in the effectiveness of the internal risk management and control systems, as is further substantiated in chapter 2 "Risk Factors", and section 4.5 "Risk Appetite & Control";

(ii) The risk- and control systems described herein, particularly in paragraph 4.5.5 "Financial Risks and Controls" provide reasonable assurance that the financial reporting does not contain any material inaccuracies;

(iii) 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

(iv) This report, particularly chapter 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 Universal Registration Document. The aforementioned statement does not in any way limit the relevance or applicability of the Risk Factors set out in this Universal Registration Document to the aforementioned period of twelve months.

/Signed on behalf of argenx SE/

Glossary

The following explanations are intended to assist the general reader to understand certain terms used in this Universal Registration Document. The definitions set out below apply throughout this Universal Registration Document, unless the context requires otherwise.

AbbVie	AbbVie S.Á.R.L.
ABSIS	autoimmune bullous skin disorder intensity score
ACA	the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010
AChR	anti-acetylcholine receptor
ADCC	antibody dependent cell-mediated cytotoxicity
ADR	American Depositary Receipt
ADS	American Depositary Share
AFM	the Dutch Authority for the Financial Markets (*Stichting Autoriteit Financiële Markten*)
AIA	America Invents Act
AgomAb	AgomAb Therapeutics NV
AKS	the U.S. federal Anti-Kickback Statute
ALS	amyotrophic lateral sclerosis
AML	acute myeloid leukemia
argenx or the Company	argenx SE
Articles of Association	our current articles of association
ASyS	anti-synthetase syndrome
ASP	average sales price
Autoantibodies	self-directed antibodies
B-cell	B lymphocyte producing a specific antibody
BioWa	BioWa, Inc
Bird Rock Bio	Bird Rock Bio, Inc.
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.
BP	bullous pemphigoid
BPCIA	the U.S. Biologics Price Competition and Innovation Act
Broteio	Broteio Pharma B.V.
C2	component 2
CBA	a collective bargaining agreement
cGMP	current good manufacturing practices
CH	Switzerland
CHMP	Committee for Medicinal Products for Human Use
Chugai	Chugai Pharmaceutical Co., Ltd.
CIDP	chronic inflammatory demyelinating polyneuropathy
Cilag	Cilag GmbH International, one of the Janssen Pharmaceutical Companies of Johnson & Johnson
CMOs	contract manufacturing organizations
CMMI	Center for Medicare and Medicaid Innovation
CMS	Centers for Medicare & Medicaid
Code of Conduct	our Code of Business Conduct and Ethics
CR	Complete remission
CRO	contract research organization
CTA	clinical trial authorization application
CTCL	cutaneous T-cell lymphoma
DCC	Dutch Civil Code
Deloitte	Deloitte Accountants B.V.
DFSA	Dutch Financial Supervision Act (Wet op het financieel toezicht)
DM	dermatomyositis
DRC	Data Review Committee
DSMB	Data Safety Monitoring Board
Dutch Corporate Governance Code	the Dutch Corporate Governance Code dated December 8, 2016, which is in force as of the financial year starting on or after January 1, 2017
EEA	European Economic Area
Elektrofi	Elektrofi, Inc.
EMA	European Medicines Authority
EMEA	Europe, Middle East and Africa
ENHANZE®	ENHANZE® technology
Enterprise Chamber	the Dutch Enterprise Chamber of the Amsterdam Court of Appeal (Ondernemingskamer van het Gerechtshof te Amsterdam)
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)
Exchange Act	the U.S. Securities Exchange Act of 1934, as amended
FairJourney	FairJourney LDA
Fc	antibody region interacting with cell surface Fc receptors
FcRn	neonatal Fc receptor
FDA	U.S. Food and Drug Administration
FDCA	the U.S. Federal Food, Drug, and Cosmetic Act
GARP	glycoprotein A repetitions predominant
GCC	Gulf Cooperation Council, comprising Saudi Arabia, Kuwait, the United Arab Emirates, Qatar, Bahrain and Oman
GCP	Good Clinical Practice
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)
Genor Biopharma	Genor Biopharma Co. Ltd
Genpharm	Genpharm Services FZ-LLC
GLP	Good Laboratory Practice
gMG	generalized myasthenia gravis

GPCR	G-protein coupled receptors
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
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
HTA	a health technology assessment
I-RODS	Inflammatory Rasch-built Overall Disability Scale
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-22	interleukin-22
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
IRB	institutional review board
ISTs	immunosuppressive therapies
ITP	immune thrombocytopenic purpura
ITP	immune thrombocytopenia
IV	intravenous
IVIg	intravenous IgG
Janssen	Janssen Pharmaceuticals, Inc.
JJDC	Johnson & Johnson Innovation – JJDC, Inc.
J-MAA	Japanese Market Authorization Application
JOBS Act	the U.S. Jumpstart Our Business Startups Act of 2012
LEO Pharma	Pharma LEO Pharma A/S
LN	lupus nephritis
Lonza	Lonza Sales AG
LUMC	Leiden University Medical Center
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
MDS	myelodysplastic syndromes
Medison	Medison Pharma Ltd.

Member State	a member state of the EEA
MET	mesenchymal-epithelial transition factor
MFN	Most Favored Nation
MG	myasthenia gravis
MHRA	Medicines and Healthcare products Regulatory Agency
Minister	Minister of Health, Labour and Welfare
MMN	multifocal motor neuropathy
MN	membranous nephropathy
MuSK	muscle-specific kinase
MSE	minimal symptom expression
myositis	idiopathic inflammatory myopathies
Nasdaq	the Nasdaq Global Select Market
NHI	National Health Insurance
NHSA	National Healthcare Security Administration
NK	natural killer
Novo	Novo Nordisk A/S
NRDL	National Reimbursable Drug List
OIG	the Office of Inspector General
OOPD	the U.S. Office of Orphan Products Development
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 and on December 15, 2021
PAA	pre-approval access program
PCT	Patent Cooperation Treaty
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
PIP	paediatric investigation plan
PK	pharmacokinetic
PMDA	Pharmaceuticals and Medical Devices Agency (Japan)
POTS	postural orthostatic tachycardia syndrome
Prospectus Regulation	Regulation (Eu) 2017/1129 Of The European Parliament And Of The Council of 14 June on the prospectus to be published when securities are offered to the public or admitted trading on a regulated market, and repealing Directive 2003/71/EC
PREA	Pediatric Research Equity Act of 2003, as amended
PRV	Priority Review Voucher
PV	pemphigus vulgaris
PVAS	pemphigus vulgaris activity score
QMG	quantitative myasthenia gravis
RDL	Reimburse Drug List
Registration Document	this universal registration document
REMS	risk evaluation and mitigation strategy

Roche	F. Hoffman-La Roche AG
RSUs	Restricted stock units
SAD	single ascending dose
SC	subcutaneous
SE regulation	European Council Regulation (EC) No 2157/2001 of October 8, 2001 on the Statute for a European company (Societas Europaea or SE)
SEC	the U. S Securities and Exchange Commission
Section 404	Section 404 of the Sarbanes-Oxley Act of 2002
Securities	Shares or American Depositary Receipts to Shares in the share capital of argenx SE
Securities Act	the U.S. Securities Act of 1933, as amended
Shire	Shire AG, now known as Shire International GmbH
SjS	Sjögren's syndrome
SLE	systemic lupus erythematosus
SMA	spinal muscular atrophy
Sopartec	Sopartec S.A.
SRD II	Directive 2017/828 of the European Parliament and of the Council of May 17, as regards the encouragement of long-term shareholder engagement
Staten	Staten Biotechnology B.V.
TEAE	treatment emergent adverse events
Takeover Law	the Belgian law dated April 1, 2007 on public takeover bids
Takeover Royal Decree	the Belgian Royal Decree of April 27, 2007 on public takeover bids
T-cell	T lymphocyte protecting the body from infection
TCL	T-cell lymphoma
TGF-β	transforming growth factor beta
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
Tregs	T-cell population modulating the immune system
U.S.	the United States of America
UCL	Université Catholique de Louvain
UK	the United Kingdom
UoT	the University of Texas System
USPTO	the United States Patent and Trademark Office
VIB	VIB vzw
V-regions	antibody variable regions
we, us or our	argenx SE together with its wholly owned subsidiaries argenx IIP BV, argenx BV, argenx US Inc, argenx Japan K.K., and argenx Switzerland SA, argenx France SAS and argenx Germany GmbH and, as applicable, its former wholly owned subsidiaries
Zai Lab	Zai Lab Limited


argenx