NewAmsterdam Pharma Company N.V.
(formerly NewAmsterdam Pharma Company B.V.)

Annual Report
for the fiscal year ended December 31, 2022

TABLE OF CONTENTS

1 INTRODUCTION

1.1 Preparation

In this report, the terms "we", "us", "our" and "the Company" refer to NewAmsterdam Pharma Company N.V. and, where appropriate, its subsidiaries.

The Company was incorporated as a Dutch private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) under the name NewAmsterdam Pharma Company B.V. on June 10, 2022. On November 21, 2022, we converted into a public limited liability company (*naamloze vennootschap)* and renamed NewAmsterdam Pharma Company N.V. in connection with the public offering of our ordinary shares and the admission to listing and trading of our ordinary shares on the NASDAQ Stock Market.

This report has been prepared by the Company's board (the "**Board**") pursuant to Section 2:391 of the Dutch Civil Code ("**DCC**") and also contains (i) the Company's statutory annual accounts within the meaning of Section 2:361(1) DCC and (ii) to the extent applicable, the information to be added pursuant to Section 2:392 DCC. This report relates to the fiscal year ended December 31, 2022 and, unless explicitly stated otherwise, information presented in this report is as at December 31, 2022.

1.2 Forward-looking statements

This report contains forward-looking statements. Forward-looking statements provide our current expectations or forecasts of future events. Forward-looking statements include statements about our expectations, beliefs, plans, objectives, intentions, assumptions and other statements that are not historical facts. Words or phrases such as “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “objective,” “ongoing,” “plan,” “potential,” “predict,” “project,” “should,” “will” and “would,” or similar words or phrases, or the negatives of those words or phrases, may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. Examples of forward-looking statements in this report include, but are not limited to, statements regarding our disclosure concerning our operations, cash flows, financial position and dividend policy.

Forward-looking statements appear in a number of places in this report and include, but are not limited to, statements regarding our intent, belief or current expectations. Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. Such statements are subject to risks and uncertainties, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, but not limited to, those identified under “*3 Risks Associated with our Business*”. Forward-looking statements in this report may include, for example, statements about:

- our public securities’ potential liquidity and trading;
- our ability to raise financing in the future;
- projected financial information, including assumptions about the efficacy of our product candidate, reimbursement and anticipated market size and market opportunity;
- our dependence on the success of our product candidate, obicetrapib, including obtaining of

regulatory approval to market obicetrapib;
- our ability to attract and retain senior management and key scientific personnel;
- our limited experience in marketing or distributing products;
- managing the risks related to our international operations;
- our ability to achieve the broad degree of physician adoption and use and market acceptance necessary for commercial success;
- our reliance on third parties for all aspects of the manufacturing of obicetrapib for clinical trials; and
- our efforts to obtain, protect or enforce our patents and other intellectual property rights related to obicetrapib.

Forward-looking statements are subject to known and unknown risks and uncertainties and are based on potentially inaccurate assumptions that could cause actual results to differ materially from those expected or implied by the forward-looking statements. Accordingly, you should not rely on these forward-looking statements, which speak only as of the date of this report. We undertake no obligation to publicly revise any forward-looking statement to reflect circumstances or events after the date of this report or to reflect the occurrence of unanticipated events, except as required by law. You should, however, review the factors and risks that we describe in the reports we file from time to time with the SEC.

In addition, statements that "we believe" and similar statements reflect our belief and opinion on the relevant subject. These statements are based on information available to us as of the date of this report. And while we believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely on these statements.

Although we believe the expectations reflected in the forward-looking statements were reasonable at the time made, we cannot guarantee future results, level of activity, performance or achievements. Moreover, neither we nor any other person assumes responsibility for the accuracy or completeness of any of these forward-looking statements. You should carefully consider the cautionary statements contained or referred to in this section in connection with the forward-looking statements contained in this report and any subsequent written or oral forward-looking statements that may be issued by us or persons acting on our behalf.

2 BUSINESS

2.1 History and development of the Company

Our legal and commercial name is NewAmsterdam Pharma Company N.V. We were incorporated as a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) under the laws of the Netherlands on June 10, 2022, solely for the purpose of effectuating the Business Combination. As part of the Business Combination, we converted our legal form to a public limited liability company (*naamloze vennootschap*) under the laws of the Netherlands on November 21, 2022. The Company is registered with the Dutch Trade Register under number 86649051. The address of our registered office is Gooimeer 2-35 1411 DC Naarden, the Netherlands and the telephone number of the

Company is +31 (0) 35 206 2971. Our agent in the United States is our subsidiary, NewAmsterdam Pharma Corporation. NewAmsterdam Pharma Corporation's address is 20803 Biscayne Blvd, Suite #105, Aventura, Florida.

On November 22, 2022 (the "Closing Date"), we consummated our previously announced business combination pursuant to the Business Combination Agreement, dated as of July 25, 2022 (the "Business Combination Agreement"), by and among the Company, FLAC, NewAmsterdam Pharma Holding B.V. ("NewAmsterdam Pharma"), and NewAmsterdam Pharma Investment Corporation, a Cayman Islands exempted company and wholly owned subsidiary of the Company ("Merger Sub").

Beginning on the day immediately prior to the Closing Date and finishing on the day immediately after the Closing Date, the following transactions occurred pursuant to the terms of the Business Combination Agreement (collectively, the "Business Combination"):

- The shareholders of NewAmsterdam Pharma ("Participating Shareholders") contributed all outstanding shares in the capital of NewAmsterdam Pharma to the Company in exchange for the issuance of ordinary shares in the share capital of the Company (the "Exchange");
- Immediately after giving effect to the Exchange, the Company's legal form was converted from a Dutch private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) to a Dutch public limited liability company (*naamloze vennootschap*) (the "Holdco Reorganization");
- After giving effect to the Exchange, Merger Sub merged with and into FLAC (the "Merger"), with FLAC surviving the merger as a wholly owned subsidiary of the Company;
- In connection with the Merger, each issued and outstanding ordinary share of FLAC was canceled and extinguished in exchange for a claim for an Ordinary Share, and such claim was then contributed into the Company against the issuance of a corresponding Ordinary Share;
- Immediately following the Merger, each outstanding warrant to purchase a Class A ordinary share, par value $0.0001 per share, of FLAC (the "FLAC Class A Ordinary Shares") became a warrant to purchase one Ordinary Share, on the same contractual terms;
- Each NewAmsterdam Pharma option that was outstanding and unexercised ("NewAmsterdam Pharma Options") remained outstanding, and to the extent unvested, such option will continue to vest in accordance with its applicable terms, and at the time of the Exchange, such NewAmsterdam Pharma Options became options to purchase, and will when exercised be settled in Ordinary Shares; and
- On the day following the Closing Date, FLAC changed its jurisdiction of incorporation by deregistering as a Cayman Islands exempted company and domesticated as a corporation incorporated under the laws of the State of Delaware (the "Domestication").

Upon the achievement of a certain clinical development milestone, we will issue to the Participating Shareholders (including Saga Investments Coöperatief U.A. ("Amgen"), an affiliate of Amgen, Inc., and Mitsubishi Tanabe Pharma Corporation ("MTPC") for this purpose) and holders of options to purchase shares of NewAmsterdam Pharma prior to the closing of the Business Combination, who were directors, officers, employees or consultants of NewAmsterdam Pharma as of the date of the Business Combination Agreement and who are at the time of achievement of such milestone providing services to the Company or its subsidiaries (the "Participating Optionholders"), 1,886,137 additional Ordinary Shares (the "Earnout Shares"), which in the case of the Participating Optionholders will take

the form of awards of restricted stock units under the LTIP. Of the total Earnout Shares 1,725,358 Earnout Shares and 160,778 Earnout Shares are currently allocated to Participating Shareholders and Participating Optionholders, respectively. The development milestone consists of the achievement and public announcement of Positive Phase 3 Data (as defined in the Business Combination Agreement) for each of NewAmsterdam Pharma's BROADWAY clinical trial and BROOKLYN clinical trial at any time during the period beginning on the date immediately prior to the Closing Date and ending on the date that is five years after the date immediately after the Closing Date, or November 23, 2027. As a result, no Earnout Shares will be issuable if the applicable milestone is not achieved within five years of the Merger.

On July 25, 2022, concurrently with the execution of the Business Combination Agreement, we and FLAC also entered into subscription agreements (each a "Subscription Agreement") with certain investors (each, a "PIPE Investor"), pursuant to which the PIPE Investors agreed to subscribe for and purchase from the Company, and the Company agreed to issue and sell to such PIPE Investors, an aggregate of 23,460,000 Ordinary Shares at $10.00 per share for gross proceeds of $234.6 million (the "PIPE Financing"). The PIPE Financing closed substantially concurrently with the Business Combination. The Ordinary Shares issued in the PIPE Financing were initially issued in reliance upon the exemption from the registration requirements of the Securities Act provided in Section 4(a)(2) of the Securities Act.

Prior to the Business Combination, we did not conduct any material activities other than those incident to our formation and certain matters related to the Business Combination, such as the making of certain required securities law filings. Upon the closing of the Business Combination, NewAmsterdam Pharma became our direct, wholly owned subsidiary, and holds all of our material assets and conducts all of our business activities and operations.

The SEC maintains a website at *http://www.sec.gov* that contains reports and other information that we file with or furnish electronically to the SEC. Our website address is *www.newamsterdampharma.com*. The information contained on our website does not form a part of, and is not incorporated by reference into, this report.

2.2 Overview & Strategy

We are a clinical-stage biopharmaceutical company developing oral, non-statin medicines for patients at high risk of cardiovascular disease ("CVD") with residual elevation of low-density lipoprotein cholesterol ("LDL-C" or "LDL"), for whom existing therapies are not sufficiently effective or well-tolerated. There exists a significant unmet need for a potent, cost-effective and convenient LDL-lowering therapy as an adjunct to statins, a class of lipid-lowering medications that are the current standard of care for high-risk CVD patients with high cholesterol. Our lead product candidate, obicetrapib, is a next-generation, oral, low-dose cholesteryl ester transfer protein ("CETP") inhibitor, that is currently in four ongoing Phase 3 and Phase 2b clinical trials as both a monotherapy and a combination therapy with ezetimibe for lowering LDL-C and preventing major adverse cardiovascular events ("MACE").

CVD is a leading cause of death worldwide and the top cause of death in the United States. ASCVD

is primarily caused by atherosclerosis, which involves the build-up of fatty material within the inner walls of the arteries. Atherosclerosis is the primary cause of heart attacks, strokes and peripheral vascular disease. One of the most important risk factors for ASCVD is hypercholesterolemia, which refers to elevated LDL-C levels within the body, commonly known as high cholesterol.

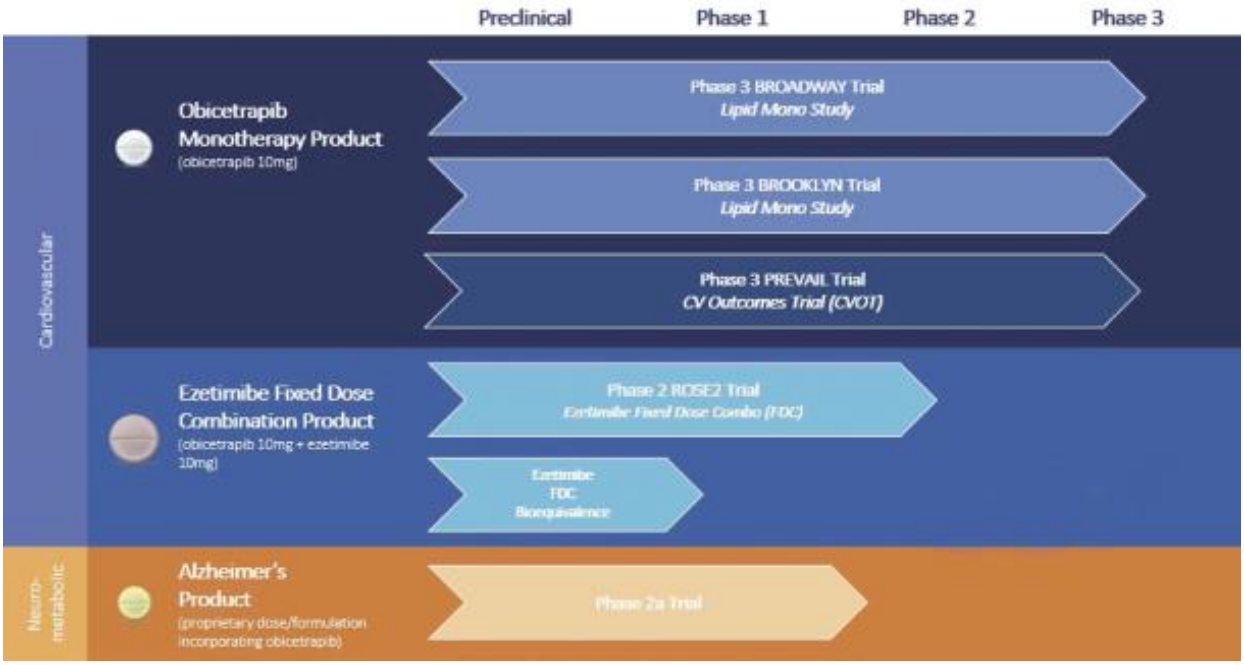
A significant proportion of patients with high cholesterol do not achieve acceptable LDL-C levels using statins alone. We estimate that there are more than 35 million patients in the United Kingdom, Germany, France, Spain and Italy (collectively, "EU5") and in the United States who are not achieving LDL-lowering goals on the current standard of care. Existing non-statin treatment options have been largely unable to address the needs of patients with high cholesterol due to modest efficacy, prohibitive pricing, or an inconvenient and painful injectable administration route. It is estimated that over 75% of ASCVD outpatients prefer oral drugs to injectable therapies.

Our product candidate, obicetrapib, is a next-generation, oral, low-dose CETP inhibitor that we are developing to potentially overcome the limitations of current LDL-lowering treatments. We believe that obicetrapib has the potential to be a once-daily oral CETP inhibitor for lowering LDL-C, if approved. In our Phase 2b ROSE trial, obicetrapib demonstrated a 51% lowering of LDL-C from baseline at a 10 mg dose level on top of high-intensity statins. In all three of our Phase 2 trials, TULIP, ROSE and OCEAN, evaluating obicetrapib as a monotherapy or a combination therapy, we observed statistically significant LDL-lowering activity combined with generally moderate side effects and no drug-related, treatment-emergent serious adverse events ("AEs"). Obicetrapib has demonstrated strong tolerability in more than 600 patients with low or elevated lipid levels ("dyslipidemia") in our clinical trials to date. Obicetrapib is also expected to be relatively low in cost to manufacture compared to most other branded LDL-lowering therapies on the market with high efficacy. We believe that the estimated low cost of goods for obicetrapib will enable favorable pricing and position it to significantly improve patient access to a high efficacy LDL-lowering therapy compared to existing non-statin treatments. Furthermore, we believe that obicetrapib's oral delivery, demonstrated activity in low doses, chemical properties and tolerability make it well-suited for combination approaches. We are developing a fixed dose combination of obicetrapib 10 mg and ezetimibe 10 mg, which we believe will demonstrate even greater potency.

Lowering of LDL-C, and particularly ApoB-containing lipoproteins, has been associated with MACE benefit in trials of LDL-lowering drugs, including the REVEAL study with the CETP inhibitor, anacetrapib. We are performing a CVOT to reconfirm this relationship.

Our goal is to develop and commercialize a LDL-lowering monotherapy and combination therapy, which offers the cost and convenience advantages of a once-daily oral pill, and fulfills the significant unmet need for an effective and convenient LDL-lowering therapy. If we obtain marketing approval, we intend to commercialize obicetrapib for patients suffering from CVD independently and with strategic partners in certain jurisdictions. We have partnered with Menarini, to provide them with the exclusive rights to commercialize obicetrapib 10 mg either as a sole active ingredient product or in a fixed dose combination with ezetimibe in the majority of European countries, if approved. Subject to receipt of marketing approval, our current plan is to pursue development and commercialization of obicetrapib in the United States ourselves, and to consider additional partners for jurisdictions outside of the United States and the European Union ("EU"), including in Japan, China and the United Kingdom.

The following table summarizes our current clinical programs:



We are conducting two Phase 3 pivotal trials, BROADWAY and BROOKLYN, to evaluate obicetrapib as a monotherapy used as an adjunct to maximally tolerated lipid-lowering therapies to potentially enhance LDL-lowering for high-risk CVD patients. We began enrolling patients in BROADWAY in January 2022 and in BROOKLYN in July 2022. We also commenced our Phase 3 PREVAIL CVOT in March 2022, which is designed to assess the potential of obicetrapib to reduce occurrences of MACE, including cardiovascular death, non-fatal myocardial infarction, non-fatal stroke and non-elective coronary revascularization. We expect to report data from our Phase 3 BROADWAY trial and our Phase 3 BROOKLYN trial in the second half of 2024. We expect to report data from our Phase 3 PREVAIL CVOT in 2026. We also expect to report data from our Phase 2 dose-finding study of obicetrapib as an adjunct to stable statin therapy in patients with dyslipidemia in Japan and our Phase 2a clinical trial evaluating obicetrapib in patients with early Alzheimer's disease in 2023.

We plan to seek approval of obicetrapib in the United States, the EU, Japan, China and the United Kingdom. We are executing multiple Phase 3 trials simultaneously, with clinical plans that incorporate feedback from the FDA, the EMA, PMDA and NMPA, including our Phase 3 BROADWAY trial and PREVAIL CVOT, which both launched in the first quarter of 2022.

We are also investigating obicetrapib as a fixed dose combination with ezetimibe, a non-statin oral LDL-lowering therapy, and plan to seek approval for this fixed dose combination in parallel with obicetrapib monotherapy. In our Phase 2b ROSE2 trial, we are evaluating the efficacy and safety of obicetrapib plus ezetimibe compared to obicetrapib and placebo alone. A fixed dose combination tablet will be evaluated in two bioequivalence studies, a pilot bioequivalence study and a potentially pivotal bioequivalence study. In the pilot bioequivalence study, which we commenced in September 2022, the bioavailability of two fixed dose combination formulations are being compared to the concomitant administration of obicetrapib and ezetimibe. After the pilot bioequivalence study, which we expect to complete in the second half of 2023, one final fixed dose combination formulation will be selected for a potentially pivotal bioequivalence study, to evaluate whether the fixed dose combination is

bioequivalent to the concomitant administration of obicetrapib and ezetimibe. In parallel to the potentially pivotal bioequivalence study, a 12-week, phase 3 efficacy and safety study will be conducted with the fixed dose combination. This study will compare the safety and efficacy of the fixed dose combination compared to placebo, obicetrapib and ezetimibe. We expect that both the potentially pivotal bioequivalence study and the phase 3 efficacy and safety study, along with the PREVAIL CVOT study, will be described in the fixed dose combination product label, if approved.

We believe that CETP inhibition may also play a role in other indications by potentially mitigating the risk of developing diseases such as Alzheimer's disease or diabetes. Evidence suggests that cholesterol accumulation in the brain is a precursor to Alzheimer's disease. For example, rodents lack the CETP gene and are resistant to Alzheimer's disease. In early preclinical studies, when the human CETP gene is knocked into a mouse, the cholesterol content of the mouse brain was observed to increase by 25% and when combined with the gene for the amyloid precursor protein, hypothesized to be a driver of Alzheimer's disease, the risk of developing Alzheimer's disease may greatly increase. In a preclinical study, we observed that CETP inhibition promoted cholesterol removal from the brain and improved cognition. We commenced a Phase 2a trial in early 2022 in patients with early Alzheimer's disease and the apolipoprotein E4 ("ApoE4") mutation to evaluate the pharmacodynamic and pharmacokinetic effects, safety and tolerability of obicetrapib. Clinically demonstrated anti-diabetic benefits have been observed with CETP inhibition in Phase 3 CVOTs that, if seen in obicetrapib, would differentiate it from current treatment alternatives, especially statins. We are planning preclinical studies to examine the potential of obicetrapib for patients suffering from diabetes and have included the onset of diabetes as an endpoint in our PREVAIL CVOT, as measured by AEs indicating Type 2 diabetes, initiation of anti-diabetes medication after confirmed diabetes diagnosis or high levels of hemoglobin A1c and fasting plasma glucose.

Our Management Team and Investors

We are led by a world-class team of industry veterans, including some of the world's preeminent cardiometabolic experts. Dr. Michael Davidson, our Chief Executive Officer and a member of our Executive Board, is a leading expert in the field of lipidology and is a seasoned executive who served as founder and Chief Executive Officer of Corvidia Therapeutics, Inc. and founder and Chief Medical Officer of Omthera Pharmaceuticals, Inc. In addition, Dr. Davidson is board-certified in internal medicine, cardiology and clinical lipidology and has extensive experience designing, managing and evaluating clinical research. Dr. John Kastelein, our founder and Chief Scientific Officer and a member of our Executive Board, is Emeritus Professor of Medicine at the Department of Vascular Medicine at the Academic Medical Center of the University of Amsterdam. Dr. Kastelein was a co-founder of uniQure N.V. and Xenon Pharmaceuticals Inc. His clinical research, on the development of novel therapies for CVD and the genetic basis of dyslipidemia is widely published, and he serves as the Chief Executive Officer of the Vascular Research Network, a site maintenance organization comprising dozens of hospitals in the Netherlands that are involved in clinical trials for cardiometabolic disease. Douglas Kling, our Chief Operating Officer, is an expert in the development of drugs to treat dyslipidemia and CVD, and has managed clinical operations at both Corvidia Therapeutics, Inc. and Omthera Pharmaceuticals, Inc.

In addition, we are backed by leading life sciences investors, including Forbion and Morningside Ventures. Prospective investors should not rely on the past investment decisions of our investors, as our

investors may have different risk tolerances and may have received their shares in prior offerings at a significant discount to the market price. See "*2.5 Operating results—Liquidity and Capital Resources—Sources of Liquidity*" for more information.

Cardiovascular Disease and Hyperlipidemia

Market Overview

According to the World Health Organization, CVD is a leading cause of death globally and was responsible for approximately 19.05 million deaths, or approximately 32% of all global deaths, in 2020. Hyperlipidemia, more commonly known as high cholesterol, has been observed to nearly double the risk of developing CVD compared to those with normal total cholesterol levels. In the United States alone, approximately 38% of adults have high cholesterol, defined as total blood cholesterol equal to or exceeding 200 mg/dL. One in 311 individuals globally are affected by genetically elevated cholesterol levels from birth, and the average age of diagnosis is approximately 44 years globally, reflecting decades of high cholesterol and resulting damage to the blood vessels.

Hypercholesterolemia underlies significant morbidity and mortality. In the United States and EU5, there are an estimated 231 million adults with hypercholesterolemia, of which we estimate 84 million are currently being treated with prescription medications. Despite the broad availability of a variety of statins capable of significantly reducing LDL-C, many patients are unable to effectively manage their cholesterol and reach their LDL-lowering goals using statins alone and therefore require additional treatment options.

We estimate that there are approximately 35 million patients in the United States and EU5 who are not achieving LDL-lowering goals on current standard of care. While there are several non-statin treatment options available, including ezetimibe, bempedoic acid (Nexletol/Nexlizet) and injectable PCSK9 inhibitors, less than one million patients are currently being treated with these medications due to product limitations relating to relatively low efficacy, side effects or market access hurdles. We believe that a potent, cost-effective, convenient, safe and well-tolerated low-dose oral medication to reduce LDL-C could fulfill this unmet need. Based on internal company estimates derived from primary market research and secondary literature, we believe that such a medication could represent a global peak annual sales potential of three to four billion dollars.

Unmet Medical Need

Elevation in LDL-C is a primary causal factor for ASCVD, and CVD outcomes in high-risk populations improve as the level of LDL-C achieved on therapy decreases. LDL-C is generally understood to be one of the most modifiable risk factors of ASCVD. Results from the Cholesterol Treatment Trialists' Collaboration have shown that lowering LDL using statin therapy reduces the risk of major vascular events (heart attacks, stroke or coronary revascularization procedures) by approximately 22% for each 40 mg/dL (one mmol/L) reduction in LDL-C achieved. A similar relationship has also been documented in non-statin CVOTs for ezetimibe, two PCSK9 inhibitors, evolocumab and alirocumab, and CETP inhibitor, anacetrapib. These trials have provided evidence that absolute LDL-C reduction and duration of therapy form a consistent model for predicting improved outcomes in patients with established ASCVD.

Despite the broad consensus regarding the causality of LDL-C for ASCVD and the CVD benefits of lipid-lowering therapies, there remains a significant clinical need for improved therapeutic regimens to achieve the goals stated by the American Heart Association ("AHA") and American College of Cardiology ("ACC") and other expert panel guidelines for lowering blood cholesterol. Although multiple classes of LDL-lowering therapies are available, there were 4.5 million deaths attributable to high LDL-C worldwide in 2020, representing a 19% increase in total number of deaths compared with 2010, based on the 2022 AHA Heart Disease and Stroke Statistical Update.

Multiple surveys have demonstrated that approximately seven out of ten patients who have been prescribed statin therapy have not reached their LDL-C goals. In a recent observational registry study in patients with ASCVD enrolled between 2016 and 2018 who primarily used statin monotherapies, only one in three patients achieved the AHA/ACC guideline-recommended LDL-C concentration of lower than 70 mg/dL.

We believe an improved LDL-C lowering therapy, particularly a well-tolerated oral therapy that may be preferred by patients, is necessary to achieve the targets established by expert panels. Patients who are at high risk for future CVD and are unable to achieve their LDL-C goals despite current standard of care are in need for an alternative oral therapy.

Our Solution: Enhanced LDL-C Lowering Through CETP Inhibition with Obicetrapib

We believe CETP inhibition with obicetrapib has the potential, if approved, to provide patients and physicians with a new oral therapy option to robustly reduce LDL-C. Obicetrapib is designed to be a next-generation, oral, low-dose CETP inhibitor with powerful LDL-lowering capability, with the potential to be delivered at a low cost to patients and payors compared with other adjuncts to statin therapy. We are developing obicetrapib as both a monotherapy and a combination therapy with ezetimibe, and have structured our obicetrapib program to overcome the safety, potency, trial design and commercial viability limitations of prior CETP inhibitors. Further, we believe that obicetrapib's oral delivery, demonstrated activity in low doses, chemical properties and potential tolerability make it well-suited for combination approaches.

Obicetrapib has intrinsic properties, such as ionizable features, substantially reduced lipophilicity, good solubility and neutral pH, that we believe give it more favorable properties as a drug candidate compared to prior CETP inhibitors. We have observed a strong tolerability profile for obicetrapib in an aggregate of over 600 patients with dyslipidemia from Phase 1 through Phase 2b clinical trials. We are conducting two Phase 3 pivotal trials, BROADWAY and BROOKLYN, to evaluate obicetrapib as a monotherapy used as an adjunct to maximally tolerated lipid-lowering therapies to potentially enhance LDL-lowering for high-risk CVD patients. We began enrolling patients in BROADWAY in January 2022 and in BROOKLYN in July 2022. We also commenced our Phase 3 PREVAIL CVOT in March 2022, which is designed to assess the potential of obicetrapib to reduce occurrences of MACE, including cardiovascular death, non-fatal myocardial infarction, non-fatal stroke and non-elective coronary revascularization. We are also investigating obicetrapib as a fixed dose combination with ezetimibe in our Phase 2b ROSE2 trial, and plan to seek approval for this fixed dose combination in parallel with obicetrapib monotherapy. We are also conducting a Phase 2 dose-finding study of obicetrapib as an adjunct to stable statin therapy in patients with dyslipidemia in Japan.

We believe obicetrapib has the potential to significantly impact the existing treatment paradigm for patients with high cholesterol contributing to CVD, and that the key differentiating attributes of our product candidate include the following:

- Enhanced LDL-C reduction capability. We believe obicetrabib's physical, pharmacokinetic and biopharmaceutical properties position it to potentially demonstrate more favorable potency and enhanced LDL-lowering capability than previous CETP inhibitors. For high-risk patient groups with high cholesterol levels that are not adequately controlled on statins, obicetrapib has been observed in clinical trials to lower LDL-C both as a monotherapy and a combination therapy with an approved cholesterol-lowering medication. In our Phase 2b ROSE clinical trial, we observed a median LDL-C reduction capability of 51% in patients treated with 10 mg obicetrapib on top of high-intensity statins.
- Promising tolerability profile. Patients are often non-compliant with existing cholesterol-lowering therapies, particularly statins, due to their side effect profiles, which results in suboptimal treatment outcomes and disease progression. In all three of our Phase 2 clinical trials of obicetrapib, we observed statistically significant LDL-lowering activity combined with generally moderate side effects and no drug-related, treatment-emergent serious AEs. In addition, clinically demonstrated anti-diabetic benefits have been observed with CETP inhibition in Phase 3 CVOTs, that, if seen in obicetrapib, could make it a potentially attractive adjunct for patients who are concerned about the risks of diabetes associated with statin therapy.
- Convenience. We believe that obicetrapib's simple once-daily, low-dose oral formulation can improve patient adherence, thereby amplifying its cholesterol-lowering impact. Additionally, unlike injectable PCSK9 inhibitors, obicetrapib can be combined with other treatments.
- Low cost of goods and patient access. We expect that the estimated low cost of goods sold for obicetrapib will enable favorable pricing compared to other drugs on the market. In addition, payor confidence is essential to ensuring access for patients. Based on the LDL-lowering activity of obicetrapib, we believe payors will perceive the LDL-lowering capability of obicetrapib to be on par with PCSK9 inhibitors, which are administered by injection, and to exceed the LDL-lowering capabilities of other existing oral therapies, and will ultimately prefer obicetrapib to existing treatment alternatives.
- Effect on other predictors of disease risk. Like other types of LDL-lowering therapies, i.e. statins and PCSK9 inhibitors, CETP inhibition enhances the removal of apolipoprotein B ("ApoB"), a protein found in lipoprotein particles that contributes to atherosclerosis. However, unlike statins, based on observations from our Phase 2 clinical trials, obicetrapib also decreases the presence of lipoprotein(a) ("Lp(a)"), an important biomarker for CVD risk reduction.

Lowering LDL-C Through CETP Inhibition

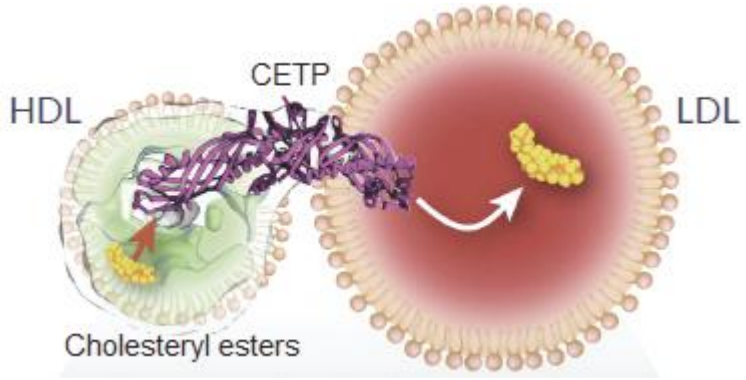
Hyperlipidemia, and in particular hypercholesterolemia or high cholesterol, is a major risk factor for atherosclerosis, which involves the build-up of fatty material within the inner walls of the arteries. This is because LDL-C is a "package" of cholesterol contained within a particle that contains ApoB. ApoB is prone to becoming trapped in the walls of arteries, leading to a build-up of fatty material, which in turn elicits a pro-inflammatory response and causes the arterial walls to stiffen. Left untreated, these deposits of fatty material can suddenly break and form a clot that causes a heart attack or a stroke. Lp(a) functions in the circulation as a "sink" for oxidized phospholipids and is also prone, like ApoB, to become trapped in the arterial wall, attached to proteoglycans of the extracellular matrix. Subsequently, these particles build up and contribute to plaque formation and inflammation. Because of the tendency

of LDL-C to build up in the arteries, LDL-C is often referred to as “bad cholesterol” and is a leading risk factor for CVD.

LDL-C and ApoB levels are mainly regulated by the liver through a surface protein known as the LDL receptor. Most current LDL-lowering therapies work by increasing the number of LDL receptors, and thereby increasing the clearance of LDL-C from the blood. Statins are the current standard of care for high-risk CVD patients with high cholesterol. Statins reduce cholesterol in the blood by blocking a key enzyme, HMG-CoA-Reductase, necessary for the synthesis of cholesterol, which reduces the amount of cholesterol made by the liver and upregulates the LDL receptor, resulting in lower blood cholesterol. PCSK9 inhibitors, another LDL-lowering treatment alternative, also increase the presence of LDL receptors by inhibiting proprotein convertase subtilisin/kexin type 9 (“PCSK9”), an enzyme involved in the degradation of LDL receptors. Two other LDL-lowering therapies, ezetimibe and Nexletol/Nexlizet, also work by upregulating LDL receptors.

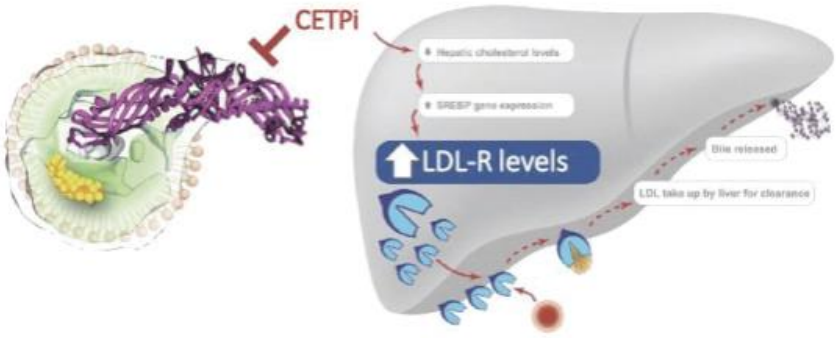
CETP is a plasma glycoprotein produced in the liver that circulates in the blood primarily bound to a high-density lipoprotein cholesterol (“HDL-C” or “HDL”) particle which can also attach to an LDL particle and form a bridge to transfer cholesterol from HDL to LDL, as shown in the figure below. CETP inhibitors, including obicetrapib, reduce LDL-C and increase HDL-C in a two-step process. In the first step, CETP inhibitors obstruct the transfer of cholesterol from HDL to LDL, immediately reducing the concentration of LDL-C in the body and increasing the concentration of HDL-C. This change in concentrations of lipid particles then produces the second step of causing the liver to produce more LDL receptors. The LDL receptor increase results in more LDL-C particles and ApoB being cleared from the bloodstream to be excreted by the digestive tract.

In animal models, CETP inhibition has been shown to block the transfer of cholesterol from HDL to LDL and to upregulate LDL receptors, thereby reducing the development of atherosclerosis and risk of ASCVD.



Although it was previously believed that the HDL-raising effects of CETP inhibition would be its primary contributor to decreased CVD risk, LDL-reduction is now known to be the most significant factor for lowering CVD risk. In a population with CETP loss of function genotypes, a 16% reduction in CVD risk was observed for every 10 mg/dL decrease in LDL-C levels. The relationship between genomic loss of CETP function and lower LDL-C levels and CVD risk is consistent with other mechanisms of genomic LDL-C reduction such as HMG-CoA reductase (statins), NPC1L1 (ezetimibe), ATP-citrate lyase (Nexletol/Nexlizet) and PCSK9 (PCSK9 inhibitors). Multiple genetic studies provide support that specific mutations associated with lifelong lower LDL-C levels reduce the risk of CVD.

CETP inhibition also increases the removal of ApoB. Apolipoproteins are proteins that are involved in packaging different types of large lipid-particle complexes that store cholesterol in the body. As shown in the figure below, the primary effect of CETP inhibition is a reduced rate of transfer of cholesteryl esters from HDL into triglyceride-rich lipoproteins, including LDL, which in turn leads to an increased concentration of cholesteryl esters in HDL and the formation of larger HDL particles. Consequently, cholesteryl esters are depleted in LDL and other ApoB-containing lipoproteins, enhancing their clearance from the body.



Limitations of Current Non-Statin Therapies

Increased attention by physicians to aggressive LDL-lowering for high-risk CVD patients has led to the increased use of non-statin medicines with LDL-lowering capabilities, including ezetimibe, Nexletol/Nexlizet and PCSK9 inhibitors, either on their own or in conjunction with statins.

However, the needs of high-risk CVD patients with high cholesterol remain largely unaddressed by current non-statin treatment options, which have only modest efficacy, are highly priced, or are inconveniently administered through an injection. In a cross-sectional study of over 20 thousand patients on lipid-lowering medication, current treatments including statins, ezetimibe, PCSK9 inhibitors or a combination of the foregoing resulted in fewer than 3% of patients reaching recommended cholesterol goals of lower than 1.8 mmol/L (70 mg/dL).

- Ezetimibe. Non-statin cholesterol-lowering medications, such as ezetimibe, function by preventing the absorption of cholesterol in the intestines by blocking the NPC1L1 protein. Although these drugs are administered at a low dose, which contributes to their safety and tolerability, and are generic and broadly available, they have been shown to only moderately reduce LDL-C. Ezetimibe has been observed to reduce LDL-C by approximately 25% compared to baseline. We believe this relatively modest efficacy supports why relatively few patients and prescribers prefer to utilize this these medications.
- Nexletol/Nexlizet. The other currently available oral non-statin, Nexletol/Nexlizet, which also inhibits an enzyme involved in cholesterol synthesis, shows only modest improvement in lowering LDL-C. Nexletol/Nexlizet has been observed to reduce LDL-C by approximately 15% compared to baseline. Along with its relatively modest efficacy, Nexletol/Nexlizet's label contains safety warnings that include tendon rupture and gout. Given that Nexletol/Nexlizet's

efficacy profile is comparable to generic ezetimibe, payors are reluctant to cover its branded price, thus limiting its access.

- PCSK9 Inhibitors. The PCSK9 inhibitors on the market are injectable, monoclonal antibodies and small interfering RNA that have been observed to reduce LDL-C levels by approximately 50% compared to baseline. While PCSK9 inhibitors have demonstrated their effectiveness at reducing LDL-C when used alone and as an adjunct to statin therapy, we believe their injectable route of administration makes them inconvenient for patients, and their access is further limited by their associated high cost and low rates of prescription approval by payors. It is estimated that over 75% of ASCVD outpatients prefer oral drugs to injectable therapies.

Limitations of Prior Attempts to Develop CETP Inhibitors

As described above, CETP inhibitors, including obicetrapib, are designed to work by blocking the transfer of cholesteryl esters from HDL to LDL, thereby directly reducing LDL-C levels in the body. We believe that CETP inhibitors can improve upon existing therapies by providing a combination of potent LDL-C lowering activity and tolerability, the ability to be administered orally and favorable pricing.

Other CETP inhibitors have reached varying stages of clinical development, but none have been approved or successfully resulted in a potent, safe and well-tolerated low-dose oral medication. We believe that the prior CETP inhibitor programs did not select optimal compounds or clinical trial designs because they focused on exploring the prominent increase in HDL-C rather than the potential for lowering LDL-C. Nevertheless, anacetrapib, the latest of the prior CETP inhibitors, provided clinical support that the absolute reduction in LDL-C over time by CETP inhibition confers a predictable benefit in the prevalence of adverse cardiovascular outcomes.

The focus on HDL-C raising by developers of prior CETP inhibitors likely resulted in the selection of chemical compounds that were not optimized for LDL-C lowering, which we believe in turn resulted in only modest reductions to CVD risk. In addition to selecting compounds that were not optimized to achieve LDL-C lowering, we believe misunderstandings about the benefits of HDL-C led to insufficient caution around compound-specific blood pressure toxicity signals, which were observed in clinical trials. For example, one CETP inhibitor, torcetrapib, resulted in off-target toxicity and increased blood pressure and aldosterone, as seen early in Phase 2 clinical trials. While another CETP inhibitor, dalcetrapib, had a favorable tolerability profile compared to torcetrapib, the drug had no LDL-lowering activity and therefore no effect on reducing adverse cardiovascular outcomes.

Prior CETP inhibitor programs also used CVOTs designed to evaluate patients with controlled rather than uncontrolled LDL-C levels. We believe the focus on HDL-C led to enrollment of patients with overly low LDL-C baseline levels, minimizing the potential to observe relative reductions in CVD risk, and that specific trials were too short for the full magnitude of MACE benefits to be observed based on the modest reduction in LDL-C achieved. For example, evacetrapib, which also had a favorable tolerability profile, used a CVOT with a median duration of only two years, which was too short to demonstrate the drug's potential to reduce CVD risk over time, and it too had only a modest observed LDL-lowering capability. Similar CVOTs with other agents that lowered LDL-C by a similar magnitude required at least three years to demonstrate a MACE benefit, including CETP inhibitor anacetrapib.

In a Phase 3 REVEAL CVOT with approximately 30,000 patients with ASCVD receiving

intensive atorvastatin therapy, for anacetrapib, its MACE benefits were observed to be predicted by the magnitude of the LDL-C reduction, suggesting that CETP inhibitors behave like statins in reducing MACE. The REVEAL trial began enrollment in August 2011 and completed its long-term follow-up in April 2019. A median four-year follow-up of the REVEAL trial showed that CETP inhibition resulted in a nine percent reduction in MACE (first major coronary event, a composite of coronary death, myocardial infarction or coronary revascularization) compared to placebo. We believe the REVEAL results provide clinical support showing that the absolute reduction in LDL-C over time by CETP inhibition confers a predictable benefit in the prevalence of adverse cardiovascular outcomes, as measured by MACE. However, due to a very low baseline level of LDL-C (61 mg/dl), the trial showed only a modest absolute LDL-C lowering of 11 mg/dl (17%). In addition, anacetrapib's commercial viability was limited by its lipophilicity, which caused it to accumulate in fat tissue over time.

We selected obicetrapib for its LDL-lowering activity and safety profile and designed our CVOT to avoid the shortcomings of prior CETP inhibitor programs and to ultimately fulfill the unmet need of patients with and at risk of CVD. Obicetrapib has intrinsic properties, such as ionizable features, substantially reduced lipophilicity, good solubility and neutral pH, that we believe give it more favorable physical, pharmacokinetic and biopharmaceutical properties as a drug candidate compared to other CETP inhibitors.

In 2022, Merck & Co. ("Merck") announced, through publication in a respected medicinal chemistry journal, the successful design of MK-8262, a CETP inhibitor with a novel molecular structure that could lead to improved LDL lowering potency at a lower dose compared to previous CETP inhibitors. Parameters that were focused on for optimization of MK-8262 were polarity and lipophilicity, oral bioavailability, better IC50 towards lower dosages and consequently better pharmacodynamics on HDL and LDL levels. Based on the published results, the program resulted in a compound that was taken through Phase 1 trials and which displayed a number of favorable characteristics in in-vitro and in-vivo studies. We believe obicetrapib shares important similarities with a number of the features of this compound, which we believe helps to explain the stronger potency at a significantly lower dose we have observed in clinical studies of obicetrapib compared to prior CETP inhibitors. Merck has announced that the compound was not advanced further due to broader strategic reasons and not due to any adverse safety or efficacy findings.

Our Strategy

Our goal is to develop and commercialize potentially transformative oral therapies for patients suffering from cardiometabolic diseases rooted in abnormal cholesterol metabolism for which existing therapies are unsuccessful or not well-tolerated.

The core elements of our strategy to achieve our goal are the following:

- ***Advance the clinical development of obicetrapib as a next-generation oral, low-dose, once-daily LDL-lowering treatment as a monotherapy and a combination therapy with ezetimibe.*** We are conducting two Phase 3 pivotal trials: BROADWAY, which began enrolling patients in January 2022, and BROOKLYN, which began enrolling patients in July 2022, to evaluate obicetrapib as a monotherapy used as an adjunct to maximally tolerated lipid-lowering therapies to potentially enhance LDL-lowering for high-risk CVD patients. We also commenced our Phase 3 PREVAIL CVOT in March 2022, designed to assess obicetrapib's potential to reduce occurrences of MACE, including cardiovascular death, non-fatal

myocardial infarction, non-fatal stroke and non-elective coronary revascularization, and a Phase 2b trial, ROSE2, to investigate obicetrapib as a fixed dose combination with ezetimibe. We are also conducting a Phase 2 dose-finding study of obicetrapib as an adjunct to stable statin therapy in patients with dyslipidemia in Japan. We expect to report data from our Phase 3 BROADWAY trial and our Phase 3 BROOKLYN trial in the second half of 2024. We expect to report data from our Phase 3 PREVAIL CVOT in 2026. We also expect to report data from our Phase 2 dose-finding study of obicetrapib as an adjunct to stable statin therapy in patients with dyslipidemia in Japan in the second half of 2023.

- ***Obtain marketing approval from regulatory agencies.*** We currently plan to seek approval of obicetrapib in the United States, the EU, Japan, China and the United Kingdom. We are executing multiple Phase 3 trials simultaneously, with clinical plans that incorporate feedback from the FDA, EMA, PMDA and NMPA. We have also initiated a Phase 2 study specifically in Japan and are including sufficient numbers of patients in Japan to support approval in those markets on the same timelines as the U.S. and Europe.

- ***Commercialize obicetrapib for the treatment of cardiometabolic disease.*** We are focused on selecting optimal partners in targeted geographies at the right time in obicetrapib's development and commercialization process. If we obtain marketing approval, both independently and, in certain jurisdictions through collaborations, we intend to commercialize obicetrapib for patients suffering from cardiometabolic disease. We have partnered with Menarini to exclusively commercialize obicetrapib 10 mg either as a sole active ingredient product or in a fixed dose combination with ezetimibe in the majority of European countries, if approved. Subject to receipt of marketing approval, our current plan is to pursue development and commercialization of obicetrapib in the United States ourselves, and to consider additional partners for jurisdictions outside of the United States and the EU, including in Japan, China and the United Kingdom.

- ***Continue advancing the clinical development of obicetrapib for the treatment of Alzheimer's disease.*** Evidence observed in our preclinical studies suggests that cholesterol accumulation in the brain may be a precursor to Alzheimer's disease. For example, rodents lack the CETP gene and are resistant to Alzheimer's disease. In early preclinical studies, when the human CETP gene was knocked into a mouse, the cholesterol content of the mouse brain was observed to increase by 25% and when combined with the gene for the amyloid precursor protein, hypothesized to be a driver of Alzheimer's disease, the risk of developing Alzheimer's disease may greatly increase. In a preclinical study, we observed that CETP inhibition promoted cholesterol removal from the brain and improved cognition. We commenced a Phase 2a clinical trial in early 2022 in patients with early Alzheimer's disease and the ApoE4 mutation to evaluate the pharmacodynamic and pharmacokinetic effects, safety and tolerability of obicetrapib. We currently expect to report data from this trial in 2023. Should the data from this trial warrant it, we intend to continue advancing this product candidate through the clinical development pathway.

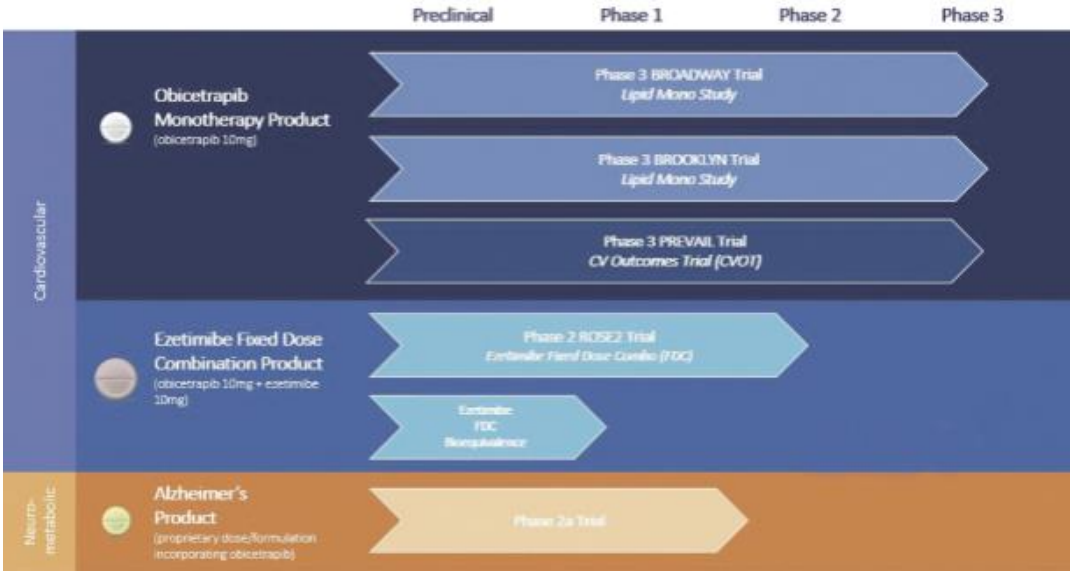
- ***Explore the potential of CETP inhibitors for use in other indications.*** We believe that CETP inhibition, by markedly increasing HDL-C and lowering LDL-C, may also have a role to play in other indications by potentially mitigating the risk of developing diseases such as diabetes, which led to an estimated 1,500,000 deaths globally in 2019, in addition to CVD and Alzheimer's disease. Clinically demonstrated anti-diabetic benefits have been observed with CETP inhibition in Phase 3 CVOTs that, if seen in obicetrapib, would differentiate it from current treatment alternatives, especially statins. We are planning preclinical studies examining the potential of obicetrapib for patients suffering from diabetes and have included the onset of diabetes as an endpoint in our CVOT.

Clinical Development Plan

We are conducting two Phase 3 pivotal trials – our BROADWAY and BROOKLYN trials – designed to measure obicetrapib's ability to reduce LDL-C as a monotherapy administered as an adjunct to maximally tolerated lipid-modifying therapy. Following our end of Phase 2 meeting with the FDA in the fourth quarter of 2021, we also commenced our Phase 3 PREVAIL CVOT for obicetrapib as a monotherapy administered as an adjunct to maximally tolerated lipid-modifying therapy in early 2022. In our Phase 2b ROSE2 trial, we are evaluating the effect of a fixed dose combination of obicetrapib 10 mg with ezetimibe 10 mg on top of high-intensity statin therapy on reduction in LDL-C. We commenced a Phase 2 dose-finding study of obicetrapib as an adjunct to stable statin therapy in patients with dyslipidemia in Japan.

Based on the lipid-modifying effects of CETP inhibition we have observed in our clinical trials for obicetrapib to date, we have conducted preclinical assessments of obicetrapib to test its potential to stimulate similar protein-modulating activity in the brain for the potential prevention and treatment of Alzheimer's disease. Following a Type B meeting in June 2021, the FDA confirmed that our preclinical data are sufficient to support a proposed clinical trial of obicetrapib for this indication, and we commenced a Phase 2a clinical trial in early 2022 in patients with early Alzheimer's disease to evaluate the pharmacodynamic and pharmacokinetic effects, safety and tolerability of obicetrapib.

We have set forth below our current obicetrapib clinical development pipeline.



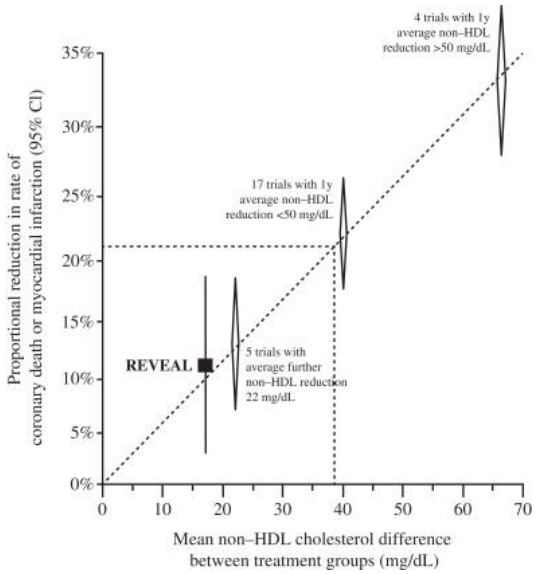
Obicetrapib for Cardiovascular Disease

There is broad scientific consensus that elevation in LDL-C is a primary causal factor for ASCVD, and CVD outcomes in high-risk populations improve as the level of LDL-C achieved on therapy decreases. A study published in the Journal of the American Medicine in 2017 found that genetic variants related to lower LDL-C levels were significantly associated with a lower risk of CVD. Specifically, the study concluded that the quantum of reduced genetic risk for CVD associated with CETP mutations was almost identical to the genetic risk of CVD observed in patients with genetically reduced levels of the proteins targeted by statins, PCSK9 inhibitors and ezetimibe. We believe the consistency of benefit

across genotypes observed in all target genes is predictive of the clinical efficacy of CETP-induced LDL-lowering on CVD.

The direct correlation between LDL-C reduction and decrease in atherosclerotic cardiovascular events has been documented for both statin as well as non-statin therapies in CVOTs for ezetimibe, the PCSK9 inhibitors evolocumab and alirocumab, and for the CETP inhibitor anacetrapib. Most notably, a median four-year follow-up of the REVEAL Phase 3 study of anacetrapib showed that CETP inhibition resulted in a nine percent reduction in MACE (first major coronary event, a composite of coronary death, myocardial infarction or coronary revascularization) compared to placebo. However, due to a very low baseline level of LDL-C (61 mg/dl), the trial showed only a modest absolute LDL-C lowering of 11 mg/dl (17%). After approximately six and a half years of total follow-up, the REVEAL clinical trial showed additional MACE reduction of 20%. The table below shows the reduction in MACE and each component of MACE in the in-trial and post-trial periods.

We believe the REVEAL results provide clinical support that the absolute reduction in LDL-C over time by CETP inhibition confers a predictable benefit in the prevalence of adverse cardiovascular outcomes, as measured by MACE. Specifically, the decrease in MACE observed in the REVEAL study of anacetrapib is consistent with the findings of The Cholesterol Treatment Trialists' ("CTT") Collaboration, illustrated in the graphic below. The CTT collaboration conducted a meta-analysis of 26 statin clinical trials and showed that there is a consistent, linear decrease in MACE for every absolute unit of non-HDL (which is primarily composed of LDL-C) cholesterol reduction. The MACE reduction observed in REVEAL falls on the meta-regression line – specifically, the CTT metaregression line predicts that an absolute reduction of LDL-C of 11 mg/dl, as seen in REVEAL, would correspond to the 9% reduction in MACE observed in REVEAL.



The graphic above presents a linear prediction of MACE benefit based on a meta-analysis of 26 prior statin clinical trials. Actual results may differ materially.

With these learnings in mind, we are executing a clinical development plan for obicetrapib focused on patients with high baseline LDL-C and that is designed to support a broad CVD label, if successful. To date, we have completed seven Phase 1 trials and three Phase 2 trials of obicetrapib. We are conducting two Phase 3 lipid trials and a third Phase 3 CVOT, and a fourth Phase 2b trial is ongoing.

Ongoing Clinical Trials for Cardiovascular Disease

Phase 3 BROADWAY and BROOKLYN Lipid Trials

We are conducting two Phase 3 pivotal trials designed to measure obicetrapib's LDL-lowering capability and plan to enroll an aggregate of 2,700 patients across both studies who require additional LDL-lowering on top of their maximum tolerated lipid-modifying therapies. Our BROADWAY trial (TA-8995-302), which began enrolling patients in January 2022, is expected to enroll approximately 2,400 patients in the United States, Europe and Asia with heterozygous familial hypercholesterolemia ("HeFH") (individuals genetically predisposed to very high cholesterol) or established ASCVD, and who have baseline LDL-C of at least 55 mg/dL, and an additional risk enhancer in participants with an LDL-C level below 100 mg/dL (including other abnormal biometrics, a recent myocardial infarction or Type 2 diabetes). Our BROOKLYN trial (TA-8995-301), which began enrolling patients in July 2022, is expected to enroll an anticipated 300 HeFH patients in the United States, Canada, Europe and Africa who have baseline LDL-C of at least 70 mg/dL. Obicetrapib will be administered in a once-daily 10 mg dose as an adjunct to diet (for regulatory purposes in the EU) and maximally tolerated lipid-modifying therapy, for a 52-week treatment period. Such lipid-modifying therapies include statins or, for statin-intolerant patients, ezetimibe, Nexletol/Nexlizet, PCSK9 inhibitors, or fibrates (a class of drugs which increase HDL-C without significantly reducing LDL-C).

The primary endpoint of both trials is percent change from baseline in LDL-C compared to placebo after 12 weeks. Secondary endpoints will also include percent changes from baseline compared to placebo after 12 weeks in Lp(a), ApoB, HDL-C, non-HDL-C (representing total cholesterol minus HDL-C), LDL-C from baseline to placebo after 180 days and 52 weeks, and, for BROADWAY, total

cholesterol and triglycerides and MACE from baseline to 30 days after the last dose. We also expect to evaluate the safety and tolerability profile of obicetrapib in a broadly representative population of adult males and females of all ages, including elderly and very elderly participants, assessed by AEs, vital signs, clinical laboratory values and electrocardiogram ("ECG") measurements as well as to evaluate the effects of obicetrapib on blood pressure.

Phase 3 PREVAIL Cardiovascular Outcomes Trial

We have also initiated our PREVAIL trial (TA-8995-304), our Phase 3 CVOT, to evaluate the effects of 10 mg obicetrapib in participants with ASCVD on MACE (cardiovascular death, myocardial infarction, stroke and non-elective coronary revascularization). We expect to enroll 9,000 participants at sites in the United States, Canada, Europe, Asia, and Australia with established ASCVD and an LDL-C level of at least 70 mg/dL, and an additional risk enhancer in participants with an LDL-C level below 100 mg/dL, whose ASCVD is not adequately controlled despite maximally tolerated lipid-modifying therapies. The planned median study follow-up is expected to be 36 months, and the treatment period will continue until the last participant has been followed for a minimum of 2.5 years after the last patient has been randomized or until the target number of 959 primary endpoint events (i.e., cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, or non-elective coronary revascularization) have occurred, whichever is later.

We have designed our PREVAIL trial based on insights gained from analyzing failures of prior CVOTs for other CETP inhibitors. Our trial design targets higher baseline LDL-C patients, which we believe creates potential for greater observed absolute LDL-C reduction, particularly given the observed median LDL-lowering activity of 51% in our Phase 2b ROSE clinical trial. We are focused on patients with high LDL-C levels and who have at least one other risk enhancer (including recent myocardial infarction, Type 2 diabetes, high triglyceride levels or low HDL-C), compared to prior CVOTs for CETP inhibitors that enrolled patients with low baseline LDL-C. We are planning for longer duration of follow-up to maximize opportunities to observe MACE reduction, with all patients to be followed for a minimum of three years. We believe that the inclusion of a high-risk patient population with established ASCVD and other risk enhancers increases the likelihood that the trial will accrue sufficient primary endpoint events over time and potentially result in a strong relative risk reduction in the treatment arm.

Phase 2b ROSE2 Trial

In our ongoing Phase 2b ROSE2 trial, we are evaluating the effect of a fixed dose combination of obicetrapib 10 mg with ezetimibe 10 mg on top of high-intensity statin therapy on reduction in LDL-C levels. This randomized, double-blind placebo-controlled trial among 114 patients with dyslipidemia is designed to compare a once-daily oral 10 mg dose of obicetrapib alone and a combination therapy with 10 mg of ezetimibe to placebo for 12 weeks. The primary endpoint is percent change in LDL-C levels from baseline.

We announced the topline results from the ROSE2 clinical trial on January 17, 2023. A total of 119 patients were randomized to receive combination therapy, obicetrapib 10mg or placebo for an 84-day treatment period. The primary efficacy endpoint was the percent change from Day 1 to Day 84 in LDL-C for the combination treatment group compared to the placebo group and was met ($p<0.0001$). Patients treated with the combination of obicetrapib and ezetimibe achieved a median reduction in LDL-C of 59%, as compared to patients treated with placebo, who achieved a median reduction in LDL-C of

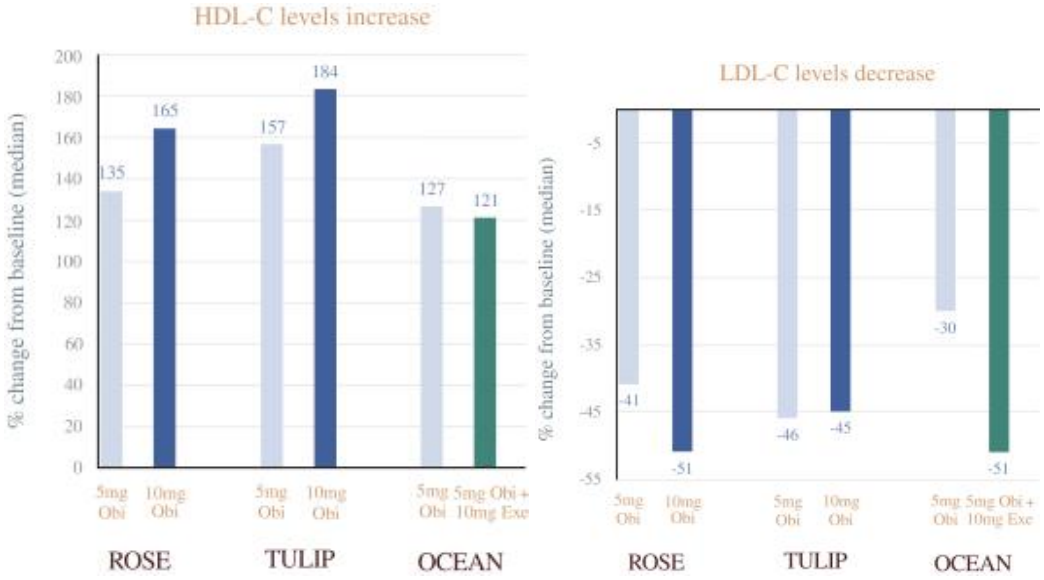
6%. Overall, the combination of obicetrapib and ezetimibe was observed to be well-tolerated, with a safety profile observed to be comparable to placebo.

Phase 2 Japan Trial

In our ongoing Phase 2 trial in Japan, we are evaluating the effects of three doses of obicetrapib (2.5 mg, 5 mg, and 10 mg) on LDL-C levels including efficacy, safety and tolerability. This is a randomized, double-blind, placebo controlled trial that is expected to enroll 108 adult Japanese patients with dyslipidemia. The trial is being conducted at hospitals and clinics across Japan. The primary endpoint is the percent change from baseline to end of treatment (day 56) in LDL-C for each obicetrapib group compared to placebo. We currently expect to report data from this trial in the second half of 2023.

Completed Phase 2 Clinical Trials

We have completed three Phase 2 trials of obicetrapib for the treatment of cardiometabolic disease. In all three trials obicetrapib was observed to robustly lower LDL-C and increase HDL-C from baseline across various treatment settings. Obicetrapib was also observed to be well-tolerated compared to placebo, in both the 5 mg and 10 mg doses and as a combination therapy with ezetimibe. The majority of treatment-emergent adverse events ("TEAEs") were mild or moderate in severity and there were no drug-related, treatment-emergent serious AEs. The graphs below summarize the results of the three Phase 2 trials.

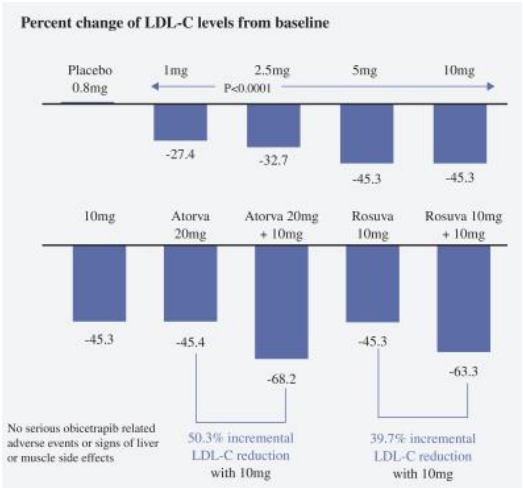


In our Phase 2b ROSE trial, we observed that obicetrapib has robust LDL-lowering capability as an adjunct to high-intensity statins at both 5 mg and 10 mg dosages. Based on our ROSE trial, we are using a 10 mg dosage for our Phase 3 trials. In our Phase 2a TULIP trial, we observed that a daily dose of up to 10 mg of obicetrapib alone significantly reduced LDL-C and increased HDL-C. Based on observations from our Phase 2b OCEAN trial, we believe that obicetrapib is at least additive for LDL lowering as a combination therapy with ezetimibe.

The table below summarizes the trial designs of the three Phase 2 trials we have completed.

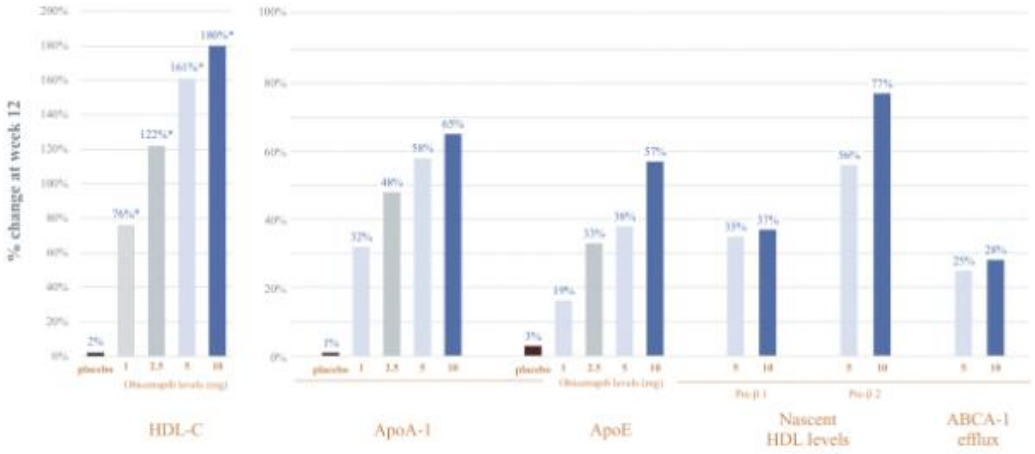
Trial	Design	Patients	Obicetrapib Formulation
TULIP (TA-8995-03)	Randomized, double-blind placebo-controlled trial to evaluate the percent changes in LDL-C and HDL-C levels	364 patients with mild dyslipidemia not on lipid-altering therapy at screening	1, 2.5, 5 or 10 mg alone and as a combination therapy with statins
ROSE (TA-8995-201)	Randomized, double-blind placebo-controlled trial to evaluate LDL-C reduction	114 patients with mild dyslipidemia already receiving high-intensity statin therapy	5 mg or 10 mg
OCEAN (TA-8995-303)	Randomized, double-blind placebo-controlled trial to evaluate LDL-C reduction	112 patients with mild dyslipidemia	5 mg alone and as a combination therapy with 10 mg ezetimibe

A Phase 2a TULIP trial of obicetrapib, which was completed in 2014, was a randomized, double-blind placebo-controlled trial among 364 patients with mild dyslipidemia and not on lipid-altering therapy at screening and involved once-daily oral dosing of obicetrapib up to 10 mg or a placebo alone and as a combination therapy with statins. The primary endpoints were the percent changes in LDL-C and HDL-C levels from baseline to week 12 of the trial, which were met for both doses. The 5 mg dose of obicetrapib resulted in a mean reduction of LDL-C by 45% and increased HDL-C by 161%, compared to placebo. In patients treated with 10 mg obicetrapib plus statin therapy (20 mg atorvastatin or 10 mg rosuvastatin), LDL-C levels were approximately 50% lower and HDL-C levels were approximately 140% higher, respectively, than those observed in patients receiving statin therapy alone.



Key secondary endpoints included percent changes in ApoB and apolipoprotein A1 ("ApoA1").

In patients treated with 5 mg obicetrapib, ApoB was reduced by 33.8%, while ApoA1 levels increased by 58.3%. A daily dose of 10 mg obicetrapib on top of statin therapy resulted in an ApoB reduction of 30% and an ApoA1 increase of 54.1% than those observed in patients receiving statin therapy alone. Other secondary endpoints included percent change in ApoE, nascent HDL levels and ABCA-1 efflux. A summary of certain of these results follows:



A total of 284 patients experienced at least one TEAE, of which 95 experienced a suspected study drug-related TEAE. For all treatment groups, the most common TEAEs were the common cold and headache (22.9% and 13.2%, respectively). Most TEAEs were mild or moderate in severity with only 13 patients experiencing a severe TEAE, two of which were suspected to be related to the study drug (one subject in the placebo group and one subject in the atorvastatin 20 mg and obicetrapib 10 mg combination). Prevalence, incidence and severity of TEAEs were similar across all treatment groups. There were eight patients with a treatment-emergent serious adverse event, none of which were study drug related, and no deaths occurred during the study.

rose

Our Phase 2b ROSE trial, which was completed in August 2021, was a randomized, double-blind placebo-controlled trial among 120 patients with mild dyslipidemia who were already receiving high-intensity statin therapy. The trial involved a once-daily oral dose of obicetrapib at either 5 mg or 10 mg dose level for eight weeks. The primary endpoint of this clinical trial was LDL-C reduction from baseline and was met for both doses. Obicetrapib had a rapid effect, with LDL-C levels dropping dramatically in the first four weeks of the study and remaining relatively steady for the remaining four weeks of the study. At the 5 mg dose level, approximately 20% of patients experienced a decrease in median LDL-C levels of over 60%; at the 10 mg dose level, that percentage nearly doubled. A summary of these statistically significant results is as follows:

Median (min, max) LDL-C levels (mg/dL) at baseline and EoT

Time	**Placebo**	**Obicetrapib 5mg**	**Obicetrapib 10mg**
Baseline Median	90.0 (63, 204) N=40	95.0 (54, 236) N=39	88.0 (39, 207) N=40
EoT Median	86.0 (43, 137)	53.0 (13, 126)	49.5 (23, 83)

Time	Placebo	Obicetrapib 5mg	Obicetrapib 10mg
	N=39	N=39	N=40
% Change from Baseline (median)	-6.5 (-53.9, 31.6) N=39	-41.45 (-71.2, 62.3) N=38*	-50.75 (-76.9, 15.6) N=40
% Change from Baseline LS mean (95% CI) P-value	-4.76 (-11.74, 2.22) 0.1814	-37.98 (-44.80, -31.17) <0.0001	-44.15 (-50.95, -37.35) <0.0001

We also observed median percent reductions in ApoB of 24.4% and 29.8%; decreases in non-HDL-C of 38.9% and 44.4%; increases in HDL-C of 135.4% and 165.0%; and decreases in Lp(a) of 33.8% and 56.5%, in each case at the 5 mg and 10 mg doses, respectively. These statistically significant results are summarized as follows:

Percent Change from Baseline to 8 Weeks in Lipid Biomarkers

		Placebo (N=40)	5 mg (N=40)	10 mg (N=40)
ApoB	Baseline:			
	n	40	40	40
	Mean (SD)	90.8 (18.2)	91.2 (22.6)	87.5 (22.0)
	Median (min, max)	87.0 (66, 136)	88.0 (53, 171)	82.0 (49, 161)
	Percent Change:			
	Mean (SD)	-4.67 (17.7)	-22.62 (21.9)	-27.19 (15.3)
	Median (min, max)	-2.60 (-50.0, 28.4)	-24.40 (-58.5, 47.4)	-29.75 (-58.4, 13.0)
	LS Mean (SE)[1]	-4.13 (2.6)	-22.40 (2.6)	-28.12 (2.6)
	p-value		<0.0001	<0.0001
Non-HDL-C	Baseline:			
	n	40	40	40
	Mean (SD)	125.4 (32.7)	125.9 (36.4)	121.4 (37.3)
	Median (min, max)	115.0 (87, 227)	118.5 (69, 276)	113.0 (53, 242)
	Percent Change:			
	Mean (SD)	-4.22 (20.4)	-34.28 (25.6)	-39.25 (17.6)
	Median (min, max)	-3.50 (-50.3, 48.4)	-38.90 (-65.6, 66.3)	-44.40 (-70.2, 22.5)
	LS Mean (SE)[1]	-3.83 (3.2)	-34.37 (3.2)	-39.86 (3.2)
	p-value		<0.0001	<0.0001
HDL-C	Baseline:			
	n	40	40	40
	Mean (SD)	48.6 (15.7)	48.5 (13.7)	49.9 (18.7)
	Median (min, max)	44.5 (19, 99)	46.5 (24, 79)	44.0 (25, 138)
	Percent Change:			
	Mean (SD)	-6.62 (12.4)	123.92 (57.7)	156.41 (52.2)
	Median (min, max)	-4.90 (-30.3, 28.6)	135.40 (-26.4, 212.9)	164.95 (55.1, 286.3)
	LS Mean (SE)[1]	-6.98 (6.6)	122.29 (6.6)	157.35 (6.5)
	p-value		<0.0001	<0.0001
Lp(a)	Baseline:			
	n	40	40	40
	Mean (SD)	108.2 (123.3)	117.1 (115.3)	85.8 (106.4)
	Median (min, max)	45.3 (2.9, 410)	89.4 (2.8, 354)	29.9 (2.8, 435)
	Percent Change:			
	Mean (SD)	5.4 (21.2)	-30.0 (31.9)	-43.2 (30.1)
	Median (min, max)	4.00 (-29.6, 45.5)	-33.8 (-84.6, 93.8)	-56.5 (-85.7, 18.3)
	LS Mean (SE)[1]	5.06 (4.4)	-30.9 (4.4)	-42.0 (4.3)
	p-value		<0.0001	<0.0001

[1] Least squares (LS) means and p-values (two-sided) are from a mixed model for repeated measures (MMRM) model with treatment, visit and treatment-by-visit as factors and baseline LDL-C as a

covariate. p-values from comparison to placebo. For percent change values, n=39 for placebo and obicetrapib 5 mg groups for all, except n=38 for LDL-C and Lp(a) for obicetrapib 5 mg.

Overall, obicetrapib as an adjunct to high-intensity statin therapy at both doses was observed to be well-tolerated compared to placebo. TEAEs were reported by 15 subjects in the 5 mg group and eight subjects in the 10 mg group, compared with 19 subjects in the placebo group. Some of the TEAEs in the study reported by more than one subject in any treatment group were muscle spasms (none in either of the obicetrapib groups and two subjects in the placebo group), fatigue (two subjects in the 5 mg group, one subject in the 10 mg group, and two subjects in the placebo group), basal cell carcinoma (none in either of the obicetrapib groups and two subjects in the placebo group), nausea (one subject in the 5 mg group and two subjects in the placebo group), Type 2 diabetes mellitus (two subjects in the 5 mg group and none in the 10 mg or placebo groups) and hypertension (two subjects in the 5 mg group and no subjects in either the 10 mg or placebo groups). All other TEAEs were experienced by only one or no subjects in each treatment group. TEAEs that were considered by the investigator to be related to study treatment were reported by three subjects (two subjects in the 5 mg group and one subject in the 10 mg group), compared with four subjects in the placebo group. There were no TEAEs leading to death. One subject in the placebo group had a TEAE leading to discontinuation. The majority of TEAEs were mild and moderate in severity; one subject in the placebo group had a severe TEAE. There were two serious TEAEs, both of which occurred in the placebo group.

Based on our ROSE trial and the enhanced LDL-C reduction capability of a 10 mg dose compared with 5 mg and the safety profile we observed, we selected a 10 mg dose for our Phase 3 lipid trials and CVOT.

ocean

Our Phase 2b OCEAN trial, which we completed in June 2021, evaluated the effect of obicetrapib as a combination therapy with ezetimibe on LDL-C levels. This randomized, double-blind placebo-controlled trial among 100 patients with mild dyslipidemia involved once-daily oral 5 mg dose of obicetrapib alone and as a combination therapy with 10 mg of ezetimibe, compared to both placebo and ezetimibe alone, for eight weeks.

The primary endpoint of the trial was percent change in LDL-C compared to baseline, which was met. We observed that obicetrapib 5 mg, ezetimibe 10 mg and their combination each significantly reduced LDL-C from baseline and compared with placebo, with statistically significant reductions compared to baseline measured at 34.4%, 14.8% and 52.0%, respectively, compared to a 1.4% reduction in the placebo group. The results are summarized as follows:

Median (min, max) LDL-C levels (mg/dL) at baseline and EOT

Time	Placebo	Ezetimibe 10mg	Obicetrapib 5mg	Obi 5 + Eze 10mg
Baseline Median	136.0 (101, 177) (N=24)	127.0 (76, 189) (N=27)	121.0 (82, 153) (N=27)	123.0 (89, 186) (N=27)
EoT Median	138.0 (88, 193) (N=25)	105.0 (66, 142) (N=24)	86.5 (38, 137) (N=26)	63.5 (34, 133) (N=24)

Time	Placebo	Ezetimibe 10mg	Obicetrapib 5mg	Obi 5 + Eze 10mg
% change from BL median	-2.0 (-24.5, 35.9) (N=27)	-14.90 (-46.8, 46.9) (N=25)	-30.10 (-56.7, 19.1) (N=25)	-51.40 (-69.6, 8.1) (N=24)
% change from BL LSMeen (95%CI) p-value	1.40 (-6.03, 8.84) **0.7116**	-12.86 (-20.29, -5.42) **0.0007**	-30.70 (-38.21, -23.19) **<0.0001**	-40.95 (-48.73, -33.16) **<0.0001**

We also observed median ApoB reductions of 23.5%, 8.9% and 34.8% for obicetrapib 5 mg, ezetimibe 10 mg and their combination, respectively, compared to 0.9% reduction in the placebo group.

Median (min, max) ApoB levels (mg/dL) at baseline and EOT

Time	Placebo	Ezetimibe 10mg	Obicetrapib 5mg	Obi 5mg + Eze 10mg
Baseline Median	105.5 (74, 141) (N=28)	103.0 (79, 133) (N=28)	102.0 (74, 124) (N=28)	105.0 (77, 158) (N=27)
EoT Median	107.0 (69, 153) (N=27)	94.0 (59, 137) (N=25)	75.0 (45, 103) (N=26)	73.0 (49, 105) (N=24)
% change from BL Median	-0.9 (-19.8, 25.4) (N=27)	-8.9 (-45.4, 32.3) (N=25)	-23.5 (-39.3, 21.2) (N=26)	-34.8 (-53.0, 8.9) (N=24)

Obicetrapib 5 mg alone and as a combination therapy with ezetimibe 10 mg taken once daily for eight weeks displayed a favorable tolerability profile. TEAEs were reported by four subjects in the obicetrapib 5 mg group and nine subjects in the combination group, compared with eight subjects in the ezetimibe 10 mg group and six subjects in the placebo group. The TEAEs in the study reported by more than one subject in any treatment group were diarrhea (no subjects and two subjects in the obicetrapib 5 mg and combination groups, respectively, and two subjects and no subjects in the ezetimibe 10 mg and placebo groups, respectively) and headache (no subjects and one subject in the obicetrapib 5 mg and combination groups, respectively, and two subjects and one subject in the ezetimibe 10 mg and placebo groups, respectively). All other TEAEs were experienced by one or no subjects in each treatment group. TEAEs that were considered to be related to study treatment were reported by one subject and three subjects in the obicetrapib 5 mg and combination groups, respectively, compared with three subjects and four subjects in the ezetimibe 10 mg and placebo groups, respectively. There were no TEAEs leading to death. One subject in the ezetimibe 10 mg group had a TEAE leading to discontinuation of the study drug, compared to no subjects in the 5 mg group and two subjects in the combination group. The majority of TEAEs were mild and moderate in severity, and one subject in the ezetimibe 10 mg group had a severe TEAE.

Phase 1 Clinical Trials

We have completed seven Phase 1 clinical trials of obicetrapib in healthy patients to date, which are summarized in the below table.

Phase 1 Trial	Design	Treatment / Formulation	Results
TA-8995-01: Single ascending dose study in healthy Caucasian and Japanese subjects	Randomized, double-blind, single-dose, placebo-controlled trial in healthy men and women. 12 groups of 8 subjects. 2 to 6 randomized to placebo or active treatment.	Single oral dose of 5, 10, 25, 50, 100 and 150 mg obicetrapib capsules, or Single oral dose of placebo	Dose-dependent and sustained inhibition of CETP activity accompanied by a decrease in LDL-C and ApoB and increases in CETP, HDL-C, ApoA-1 and apolipoprotein E ("ApoE"). Pharmacokinetics and pharmacodynamics generally consistent across ethnicity, age and gender.
TA-8995-E02: Multiple ascending dose study in healthy subjects	Randomized double-blind, placebo-controlled, sequential, multiple ascending-dose design. 5 groups of 12 subjects randomized to placebo or active treatment. Duration of treatment: 28 days of dosing for group 1, 21 days for groups 2-5.	Multiple oral dosages of 5, 10, 2.5, 1, and 25 mg obicetrapib capsules, or Multiple oral dosages of placebo	No safety or tolerability issues observed. Single and multiple doses of up to 25 mg of obicetrapib did not yield adverse effects on vital signs or ECG changes, nor did clinical laboratory assessments and physical examinations reveal any safety issues. The maximum percent reduction in CETP activity from baseline following the 5 mg and 10 mg doses were 90.9% and 97.6%, respectively.
TA-8995-07: Study to assess the mass balance recovery, pharmacokinetics, metabolism and excretion of ^{14}C-TA-8995 in healthy male subjects	Open label, single oral dose study in 6 subjects.	10 mL ^{14}C-obicetrapib oral suspension, containing 10 mg and 100 µCi of ^{14}C-obicetrapib	Obicetrapib was steadily absorbed with a median of 4.5 hours to maximum absorption levels. Median half-life was 161 hours. A mean of 63.8% radioactivity was recovered in the feces

Phase 1 Trial	Design	Treatment / Formulation	Results
			and 15.4% in the urine, Overall total recovery of radioactivity in excreta approximately 78% of the administered dose.
TA-8995-04: Study of the electrocardiographic effects of TA-8995 in healthy male and female subjects	135 subjects randomized to one of 3 study treatments.	Single oral dose of 150 mg obicetrapib capsules, or Single oral dose of placebo, or Single open-label oral dose of 400 mg moxifloxacin	No clinically meaningful effects on any ECG parameter were observed.
TA-8995-05: A Phase 1, open label study to assess the effects of TA-8995 on the pharmacokinetics of midazolam and digoxin in healthy male subjects	Open label, crossover, fixed sequence study in 16 healthy male subjects. Duration of treatment up to 15 days.	Digoxin 0.25 mg oral tablet on the morning of Days 1 and 13 Midazolam 5 mg oral solution on the morning of Days 2 and 14 obicetrapib 25 mg (2 x 10 mg and 1 x 5 mg) oral capsules on the morning of Day 8 and 10 mg oral capsule on the morning of Days 9 to 15.	No significant effect on digoxin was observed, with a statistically significant decrease in midazolam plasma. Absorption rates of digoxin and midazolam were unaffected by the presence of multiple doses of obicetrapib.
TA-8995-08: Bioequivalence study of capsule and tablet formulations of TA-8995 in healthy male subjects	Open-label, randomized, 2 treatment period (3 days), cross-over study in 26 subjects	5 mg obicetrapib orally, either as a capsule or as a tablet in the first treatment period, and vice versa in the second treatment period.	Obicetrapib formulated as a tablet was bioequivalent to obicetrapib formulated as a capsule in terms of overall concentration over time but not in terms of the maximum observed concentration, which varied among study subjects.
TA-8995-06: A Phase 1 study of the effects of TA-8995 on Lp(a) in male and female subjects with elevated Lp(a)	Single-center, randomized, double-blind, placebo-controlled, parallel-group	TA-8995 10 mg once daily, TA-8995 2.5 mg once daily, or matching placebo once daily.	There were statistically significant reductions in Lp(a) in both the TA-8995 2.5 mg and 10 mg groups, compared with placebo, at week 12 (primary endpoint)

Phase 1 Trial	Design	Treatment / Formulation	Results
			and at week 4 (secondary endpoint). There were statistically significant increases in HDL-C, ApoA1, and ApoE levels and decreases in LDL-C and ApoB levels, at week 12, for both the TA-8995 2.5 mg and 10 mg groups, compared with placebo. TA-8995 2.5 mg and 10 mg once daily for 12 weeks was generally well tolerated in subjects with elevated Lp(a) levels.
TA-8995-09: A randomized, open-label, two-sequence, two-period, two-treatment crossover study to evaluate the effect of food on the bioavailability of obicetrapib tablets in healthy adult subjects	Open-label, single-dose, randomized, 2-sequence, 2-period, 2-treatment crossover study in 30 subjects	10 mg obicetrapib tablets orally administered either after an overnight fast of at least 10 hours (Treatment T1, fasted) or at 30 minutes after the start of a completed standardized high-fat, high-calorie breakfast that was preceded by an overnight fast of at least 10 hours (Treatment T2, fed)	Based on the plasma concentration data for obicetrapib, the peak and overall systemic exposure were 55-59% greater under fed conditions compared to that of fasted conditions. The least-squares geometric mean of fed versus fasted ratios were 154.87%, 155.42% and 158.53% for AUC0-t, AUC0-∞ and C_{max}, respectively.

Obicetrapib for Other Therapeutic Areas

Alzheimer's disease

According to the World Health Organization, Alzheimer's disease and other dementias affect approximately 55 million people as of 2021, and this is expected to increase to 78 million in 2030 and 139 million in 2050. Alzheimer's disease is the most prevalent form of dementia, resulting in the generalized degeneration of the brain.

In a healthy brain, excess cholesterol levels in the neurons and amyloid-beta ("Ab") peptide removal from cerebral spinal fluid are regulated properly. The brain is the most cholesterol-rich organ in the body; comprising only two percent of the body's mass, it contains approximately 20% of the body's cholesterol, which is recycled and redistributed through an ApoE-mediated lipoprotein pathway. Inside populations of cells called astrocytes, ApoE binds with cholesterol that has been released into the

brain by neurons and converts it into a different form of cholesterol that is transported out of the brain into the systemic circulation. In addition to ApoE, the protein associated with HDL, ApoA1, also acts as the brain's "vacuum cleaner," by removing toxic cholesterol from peripheral tissue to promote healthy cell function and survival. In addition, small HDL particles that transverse the blood brain barrier remove excess Ab peptides in cerebral spinal fluid for ultimate conversion and transport out of the brain.

Alzheimer's disease, however, is characterized in part by the aggregation of Ab peptides into amyloid plaques in cerebral spinal fluid, facilitated by the presence of excess cholesterol in cell membranes. Thus, the accumulation of cholesterol in cell membranes and the ineffective clearance of Ab plaques by ApoE and ApoA1 in their HDL forms is associated with the development of Alzheimer's disease. Importantly, certain forms of ApoE (in particular, ApoE4) are worse at Ab transport than others, such as ApoE2, and are known to be associated with an increased risk of Alzheimer's disease. Further, CETP activity has been detected in astrocytes, the cells where ApoE bind with cholesterol, indicating the potential for a CETP inhibitor to function in the brain similarly to its lipid-modifying effects in the cardiovascular system. Genetic studies have shown that CETP loss of function mutations mitigate the risk of Alzheimer's disease in patients with the ApoE4 genotype.

Based on these observations as well as the marked increases of ApoA1 observed in our Phase 2 clinical trials and the increases in ApoE observed in the TULIP trial, we have conducted preclinical assessments of obicetrapib for the prevention and treatment of Alzheimer's disease. In initial animal testing, we observed, in preliminary data, a statistically significant reduction in Ab42 over the total Ab ratio in the CSF of mice, a biomarker of Alzheimer's disease activity.

Following a Type B meeting in June 2021, the FDA confirmed that our preclinical data are sufficient to support a proposed clinical trial of obicetrapib for the prevention and treatment of Alzheimer's disease. We commenced a Phase 2a clinical trial in early 2022 in patients with early Alzheimer's disease and the ApoE4 mutation to evaluate the pharmacodynamic and pharmacokinetic effects, safety and tolerability of obicetrapib. In this trial, obicetrapib at a 10 mg dose is being administered orally for 24 weeks, and the primary endpoints being evaluated are the change in levels of apolipoproteins in plasma and cerebrospinal fluid from baseline to the end of the 24-week trial period.

Manufacturing and Supply

We currently have no manufacturing facilities and limited personnel with manufacturing experience. We rely on a single contract manufacturer to produce both drug substances and drug products required for our clinical trials. Obicetrapib 5 and 10 mg tablets are manufactured and tested in accordance with Good Manufacturing Practice, at facilities in the United States, Italy and the United Kingdom.

Marketing and Sales

We do not currently have our own marketing, sales or distribution capabilities. In order to commercialize obicetrapib or any future product candidates, if approved for commercial sale, we currently plan to develop our own sales and marketing infrastructure in the United States and have entered, and expect to continue to enter, into arrangements with third parties to perform these services outside of the United States. We may also opportunistically seek strategic collaborations to maximize the commercial opportunities for our future product candidates inside and outside the United States. We

have entered into a license agreement with Menarini, pursuant to which Menarini has been granted the exclusive rights to commercialize obicetrapib 10 mg either as a sole active ingredient product or in a fixed dose combination with ezetimibe in the majority of European countries, if approved. As any future product candidates near regulatory approval and potential commercial launch, we plan to assess our options for commercializing each respective product candidate and may choose to commercialize themselves ourselves or with a partner.

Menarini License

On June 23, 2022, we entered into the Menarini License, pursuant to which we granted Menarini an exclusive, royalty-bearing, sublicensable license under certain of our intellectual property and our regulatory documentation to undertake post approval development activities and commercialize multiple brands of obicetrapib in a single unit dose of 10 mg or less, either as a sole active ingredient product or in a fixed dose combination with ezetimibe (the "Licensed Products"), for any use in the majority of European countries (the "Menarini Territory"). We retained all rights to obicetrapib in all other territories and in other dosages.

We are solely responsible for conducting the development activities to obtain regulatory approval for obicetrapib. Menarini may conduct market access studies, medical affairs activities, non-registration studies and Phase IV clinical trials in the Menarini Territory. Menarini will be responsible for submitting and obtaining the required regulatory approvals to commercialize obicetrapib (at the licensed dosage) in the Menarini Territory and will own the regulatory approvals, if received. Menarini will also be solely responsible for commercializing obicetrapib (at the licensed dosage), if approved, and will be required to use commercially reasonable efforts to commercialize obicetrapib in the Menarini Territory.

Pursuant to the Menarini License, Menarini made an upfront payment to us of €115.0 million. Menarini has also committed to providing €27.5 million in funding for our research and development activities over several years, together with bearing 50% of any development costs incurred in respect of the pediatric population in the Menarini Territory. We are also eligible to receive up to an additional €863 million upon the achievement of various clinical, regulatory and commercial milestones. If obicetrapib is approved and successfully commercialized by Menarini, we will be entitled to tiered royalties ranging from the low double digits to the mid-twenties as a percentage of net sales in the Menarini Territory, with royalty step-downs in the event of generic entrance or in respect of required third-party intellectual property payments.

The Menarini License will expire on the last to expire royalty term, which is determined on a licensed product-by-licensed product and country-by-country basis, and is the later of (i) the expiration of the last to expire licensed patent that includes a valid claim in the country, (ii) expiration of regulatory exclusivity granted by the prevailing governmental authority for the licensed product in the country or (iii) 12 years from the first commercial sale of the licensed product in the country.

In addition, Menarini is expected to purchase obicetrapib and ezetimibe product from us in accordance with a supply agreement to be entered into by Menarini and us (the "Supply Agreement"). We will supply all required quantities of obicetrapib and ezetimibe product for the Menarini Territory as set forth in the Supply Agreement.

Through December 31, 2022, we had not received any milestone payments from Menarini under the Menarini License. In January 2023, we achieved a clinical success milestone related to our Phase 2b ROSE2 clinical trial which resulted in receiving a milestone payment from Menarini in April 2023 amounting to €5 million.

Intellectual Property

Our future commercial success depends, in part, on our ability to obtain and maintain patent and other proprietary protection for commercially important inventions, to obtain and maintain know-how related to our business, including our product candidates, to defend and enforce our intellectual property rights, in particular our patent rights, to preserve the confidentiality of our trade secrets, and to operate without infringing, misappropriating, or violating the valid and enforceable patents and other intellectual property rights of third parties. Our ability to preclude or restrict third parties from making, using, selling, offering to sell, or importing competing molecules to our products may depend on the extent to which we have rights under valid and enforceable patents and trade secrets that cover these activities.

We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

We strive to protect and enhance our proprietary inventions and improvements that we consider commercially important to the development of our business, including by seeking, maintaining, and defending U.S. and foreign patent rights. All of the issued patents and pending patent applications in our patent portfolio are owned by our subsidiary, NewAmsterdam Pharma B.V., Dutch Chamber of Commerce registry number 55971946. As of December 31, 2022, we owned seven issued U.S. patents and nine pending U.S. patent applications. We also owned 98 granted European patents and three pending European patent applications, two granted Chinese patents and seven pending Chinese patent applications. In addition, we owned 74 granted patents and 31 pending patent applications in other foreign jurisdictions, including international applications under the Patent Cooperation Treaty, or PCT.

The patent positions of pharmaceutical companies are generally uncertain and can involve complex legal, scientific, and factual issues. We cannot predict whether any patent applications we pursue will issue as patents in any particular jurisdiction, or whether the claims of any issued patents will provide sufficient proprietary protection from competitors.

In addition, the coverage claimed in a patent application may be significantly reduced before a patent is granted, and its scope can be reinterpreted and even challenged after issuance. As a result, we cannot guarantee that any of our products will be protected or remain protectable by enforceable patents. Moreover, any patents that we license or may own in the future may be challenged, circumvented, or invalidated by third parties. In addition, because of the extensive time required for clinical development and regulatory review of a product candidate we may develop, it is possible that, before our product candidate can be commercialized successfully, any related patents may expire or remain in force for only a short period following commercial launch, thereby limiting the protection such patent would afford the applicable product and any competitive advantage such patent may provide.

For any individual patent, the term depends on the applicable law in the country in which the patent is issued. In most countries where we have patents and patent applications, including the United States, patents have a term of 20 years from the application filing date or earliest claimed nonprovisional priority date. In the United States, the patent term may be shortened if a patent is terminally disclaimed over another patent that expires earlier. The term of a U.S. patent may also be lengthened by a patent term adjustment that is awarded by the USPTO, in order to address administrative delays by the USPTO in examining and granting a patent.

In the United States, the term of a patent that covers an FDA-approved drug may be eligible for patent term extension in order to restore the period of a patent term lost during the premarket FDA regulatory review process. Specifically, the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") permits a patent term extension of up to five years beyond the natural expiration of the patent (but the total patent term, including the extension period, must not exceed 14 years following FDA approval). The patent term extension period granted on a patent covering a product is typically one-half the time between the effective date of a clinical investigation involving human beings is begun and the submission date of an application, plus the time between the submission date of an application and the ultimate approval date. Only one patent applicable to an approved product is eligible for patent term extension, and only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended. The application for patent term extension must be submitted prior to the expiration of the patent. The USPTO reviews and approves the application for any Patent Term Extension in consultation with the FDA.

Prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the USPTO and other patent offices may be significantly revised before issuance, if granted at all.

For more information regarding the risks related to our intellectual property, please see "*3 Risks Associated with our Business—Intellectual Property*."

The issued patents and patent applications for obicetrapib are detailed below.

Obicetrapib First Generation Patents

The patent portfolio for obicetrapib composition of matter includes a first generation patent family directed generally to compounds, pharmaceutical compositions comprising the compounds, and methods of treatment using the compounds and pharmaceutical compositions. We have two granted patents in the United States covering a genus of compounds that includes obicetrapib and claims that more narrowly cover the obicetrapib compound, pharmaceutical compositions, and methods of treatment. We have 17 granted patents in Europe. In Asia, we have one granted patent in China, two granted patents in Japan, one granted patent in the Republic of Korea, one granted patent in Taiwan and one granted patent in Singapore. We have one granted patent in India.

In North America outside of the United States, we have one granted patent in Canada and one granted patent in Mexico. In addition we have 13 granted patents in other foreign jurisdictions. Patent applications are pending in Argentina and Thailand. Patents, and patent applications, if granted, are expected to expire between April 2025 and August 2027, without taking potential patent term extensions

into account. The first generation portfolio also includes a patent family covering a method of synthesizing obicetrapib. We have one patent in the United States, five patents in Europe including the United Kingdom, and one patent in Japan. Patents in this family are expected to expire between March 29, 2027 and March 31, 2029, not including patent term extensions.

Obicetrapib Second Generation Patents

Our second generation obicetrapib patent portfolio includes a patent family directed to solid oral dosage forms containing 5 to 10 mg of obicetrapib, including tablet forms, and methods of treatment comprising administration of 1 to 25 mg of obicetrapib daily. We have two granted patents in the United States and a pending application. We have 38 granted patents in Europe. In Asia, we have no granted patents in China, one granted patent in the Republic of Korea, one granted patent in Japan, one granted patent in Taiwan, one granted patent in Singapore and one granted patent in Hong Kong. We have one granted patent in India. In North America outside of the United States, we have one granted patent in Mexico and one granted patent in Canada. In addition, we have 16 granted patents in other foreign jurisdictions. Patent applications are pending in Argentina, Brazil, China, Hong Kong, Colombia, Costa Rica, Egypt, Libya, Peru, Thailand and Venezuela. Patents, and patent applications, if granted, are expected to expire in February 2034, without taking potential patent term extensions or patent term adjustment into account.

We also have a patent family directed to compositions that contain obicetrapib and a statin, methods of treating with compositions that contain obicetrapib and a statin, and in Europe and other foreign jurisdictions, methods of use in which obicetrapib and a statin are separately administered. We have one granted patent in the United States and an application to reissue the patent with additional claims covering separate administration of obicetrapib and a statin. We have no granted patents in Europe. In Asia, we have no granted patents in China, one granted patent in Japan and two granted patent in Taiwan. In North America outside of the United States, we have one granted patent in Mexico. In addition, we have two granted patents in other foreign jurisdictions. Patent applications are pending in China, Hong Kong, Japan, Republic of Korea, Thailand, Canada, Europe and Venezuela. Patents, and patent applications if granted, are expected to expire between February 2034 and August 2035, without taking potential patent term extensions or patent term adjustment into account.

In addition, we have a patent family that claims a synthetic intermediate used in the synthetic process we intend to use commercially, as well as processes to make that intermediate. We have one issued US patent and 39 granted patents in Europe. In Asia, we have one granted patent in China, one granted patent in Hong Kong, one granted patent in Japan, one granted patent in Singapore, one granted patent in Taiwan and one granted patent in India. In North America outside of the United States, we have one granted patent in Mexico and one granted patent in Canada. In addition, we have 14 granted patents in other foreign jurisdictions. Patent applications are pending in Argentina, Brazil, Europe, Republic of Korea and Venezuela. Patents, and patent applications if granted, are expected to expire in July 2035, without taking potential patent term extensions or patent term adjustment into account.

Obicetrapib Third Generation Patents

We have one pending US provisional application covering the solid salt form of obicetrapib that we intend to commercialize and the process for its commercial synthesis. Patents, and patent applications if granted, are expected to expire in July 2043, without taking potential patent term extensions or patent

term adjustment into account.

We also have patent families, all of which consist of pending patent applications, directed to compositions and methods of use of obicetrapib as a combination therapy with (i) ezetimibe, (ii) statins for use in certain subpopulations of patients, and (iii) SGLT2 inhibitors. Patents, if granted, are expected to expire respectively in (i) February 2042, (ii) July 2042, and (iii) December 2042, without taking potential patent term extensions or patent term adjustment into account. We have three patent families, each consisting of a US provisional application, covering our ongoing phase 2 trials and upcoming phase 3 trial protocols. Patents, if granted, are expected to expire in 2043.

In addition, we have two patent families covering methods of using obicetrapib to treat neurodegenerative diseases. The first of these families currently consists of a pending international PCT application and a pending European application. The second consists of a US provisional application. Any patents that grant from these families will expire respectively in March 2042 and September 2043, without taking into account potential patent term extensions or patent term adjustments.

Trade Secrets

We also rely on trade secrets, know-how, confidential information and continuing technological innovation to develop, strengthen and maintain our proprietary position in our field and protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. However, trade secrets can be difficult to protect. While we take measures to protect and preserve our trade secrets, such measures can be breached, and we may not have adequate remedies for any such breach. We seek to protect our proprietary information, in part, using confidentiality agreements and invention assignment agreements with our collaborators, employees and consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. We cannot guarantee, however, that we have executed such agreements with all applicable counterparties. Furthermore, these agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors and other third parties, or misused by any collaborator to whom we disclose such information. To the extent that our collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For more information regarding the risks related to our intellectual property, please see "*3 Risks Associated with our Business—Intellectual Property*."

Competition

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our potential competitors include large pharmaceutical companies, smaller biotechnology and specialty pharmaceutical companies and generic drug companies. Many of our potential competitors have greater financial and technical human resources than we do, as well as greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products, and the commercialization of those products. Accordingly, our potential competitors may be more successful than us in obtaining FDA-approved drugs and achieving widespread market acceptance. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. Finally, the development of new treatment methods for the diseases we

are targeting could render our product candidates non-competitive or obsolete.

We believe the key competitive factors that will affect the development and commercial success of our obicetrapib product candidate, if approved, will be its enhanced LDL-lowering capability as a monotherapy or as a combination therapy, tolerability profile, convenience of oral dosing, price and availability of reimbursement from governmental and other third-party payors, and effect on other predictors of disease risk.

We are currently developing obicetrapib primarily for the treatment of patients at high cardiovascular risk with elevated levels of LDL-C as an adjunct to statins. If approved, obicetrapib would compete with approved non-statin treatments such as ezetimibe, Nexletol/Nexlizet and PCSK9 inhibitors such as Repatha, Praluent and Leqvio. There are also a number of product candidates in clinical development by third parties, such as Amryt Pharma, Arrowhead Pharmaceuticals, AstraZeneca, CVI Pharmaceuticals, Innovent Biologics, Ionis Pharmaceuticals, Matinas BioPharma, Merck, Novartis, Novo Nordisk, Regeneron Pharmaceuticals and others, that are intended to treat CVD.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing, and export and import of drug products. We, along with any third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval of our products and product candidates. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the FDCA, as amended, and its implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. A new drug must be approved by the FDA through the NDA process before it may be legally marketed in the United States, and this process generally involves the following:

- completion of preclinical laboratory tests, animal studies, and formulation studies in accordance with FDA's Good Laboratory Practice requirements and other applicable regulations;
- submission to the FDA of an IND application, which must become effective before human clinical trials may begin and must be updated annually and when certain changes are made;
- approval by an independent IRB, or independent ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with GCPs, to establish the safety and efficacy of the proposed drug for its intended use;
- preparation of and submission to the FDA of an NDA after completion of pivotal trials;

- a determination by the FDA within 60 days of its receipt of an NDA to file the application for review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA audit of the nonclinical study and/or clinical study sites that generated data in support of the NDA; and
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States.

Prior to beginning the first clinical trial with a product candidate in the United States, a sponsor must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product; chemistry, manufacturing and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. Some long-term preclinical testing may continue after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial or not allowing it to commence on the terms originally specified in the IND.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, dosing procedures, subject selection and exclusion criteria, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated

objectives. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

A sponsor who wishes to conduct a clinical trial outside of 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 must ensure that the clinical trial complies with regulatory requirements if the data is to be used in support of NDA approval. The FDA will accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the trial was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection, if deemed necessary.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: The product candidate is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism, excretion and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- Phase 2: The product candidate is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages, and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3: The product candidate is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy, and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval and labeling. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be conducted after initial marketing approval and may be used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality, and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected AEs, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

In addition, during the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

U.S. Review and Approval Process

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical, and other nonclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling, and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by independent investigators. To support marketing approval, the data submitted must be sufficient to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. The submission of an NDA is subject to the payment of user fees; a waiver of such fees may be obtained under certain limited circumstances.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once accepted for filing, the FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality, and purity. Under the Prescription Drug User Fee Act ("PDUFA"), guidelines that are currently in effect, the FDA has a goal of ten months from the filing date to complete its initial review and act on a standard NDA for a drug that is a new molecular entity, and of ten months from the date of NDA receipt to review and act on a standard NDA for a drug that is not a new molecular entity. The FDA does not always meet its PDUFA goal dates, and the review process is often extended by FDA requests for additional information or clarification.

The FDA may refer an application for a novel drug to an advisory committee. 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.

Before approving an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP and adequate to assure consistent production of the product within designated specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs and assure the integrity of the clinical data submitted to the FDA. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates an NDA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter ("CRL"). An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete and the application is not ready for approval. A CRL will describe all of the deficiencies that the FDA has identified in the NDA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the NDA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of an NDA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA with a Risk Evaluation and Mitigation Strategy ("REMS"), to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. The FDA may also require one or more Phase 4 post-marketing studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies or surveillance programs.

In addition, the PREA requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of

administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current, or fails to submit a request for approval of a pediatric formulation.

U.S. Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. For example, the Fast Track program is intended to expedite or facilitate the process for reviewing new products that are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a Fast Track designated product has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the product candidate may be eligible for priority review. A Fast Track-designated product may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted. Rolling review may occur if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for Breakthrough Therapy designation to expedite its development and review. A product candidate can receive Breakthrough Therapy designation if preliminary clinical evidence indicates that the product candidate, alone or as a combination therapy with one or more other drugs 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 designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

A marketing application for a drug submitted to the FDA for approval, including a product candidate with a Fast Track designation and/or Breakthrough Therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review. A product candidate is eligible for priority review if it is designed to treat a serious condition, and if approved, would provide a significant improvement in safety or effectiveness compared to available alternatives for such disease or condition. For new-molecular-entity NDAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date, or with respect to non-new-molecular-entity NDAs, within six months of the NDA receipt date.

Additionally, product candidates studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may utilize an accelerated approval pathway upon a determination that the product has an effect on (1) a surrogate endpoint that is reasonably likely to predict clinical benefit or (2) a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Products receiving accelerated approval may be subject to withdrawal of its approval if, for example, the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, for products being considered for accelerated approval, the FDA generally requires, unless otherwise informed by the agency, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency for review during the pre-approval review period, which could adversely impact the timing of the commercial launch of the product.

Fast Track designation, Breakthrough Therapy designation, priority review designation, and the accelerated approval pathway do not change the scientific or medical standards for approval or the quality of evidence necessary to support approval, but may expedite the development or review process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

U.S. Marketing Exclusivity

Market exclusivity provisions under the FDCA can delay the submission or the approval of certain marketing applications. The FDA provides periods of non-patent regulatory exclusivity, which provides the holder of an approved NDA limited protection from new competition in the marketplace. Five years of exclusivity are available to new chemical entities ("NCEs"). An NCE is a drug that contains no active moiety that has been approved by the FDA in any other NDA. An active moiety is the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt, including a salt with hydrogen or coordination bonds, or other noncovalent, or not involving the sharing of electron pairs between atoms, derivatives, such as a complex (i.e., formed by the chemical interaction of two compounds), chelate (i.e., a chemical compound), or clathrate (i.e., a polymer framework that traps molecules), of the molecule, responsible for the physiological or pharmacological activity of the drug substance. During the exclusivity period, the FDA may not accept for review or approve an ANDA, or a 505(b)(2) NDA submitted by another company that contains the same active moiety. An ANDA or 505(b)(2) application, however, may be submitted one year before NCE exclusivity expires if a Paragraph IV certification of patent invalidity, unenforceability, or non-infringement is filed.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers

only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active ingredient for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a 505(b)(1) NDA; however, an applicant submitting a 505(b)(1) NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

The FDA may also grant pediatric exclusivity, which provides a six-month extension to existing regulatory or patent exclusivity. To be eligible for pediatric exclusivity, FDA must issue a Written Request detailing the studies to be performed and the timeframe for their completion. If an applicant agrees to perform the studies as outlined in the Written Request, the applicant must submit study reports at least nine months prior to the expiry of the exclusivity that is to be extended. The study reports must demonstrate that the applicant has met the conditions of the Written Request.

U.S. Post-approval Requirements

Drug products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. In rare cases, pre-approval of promotional materials may be required. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. Further, for certain modifications to the drug, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain prior FDA approval of a new NDA or NDA supplement, which may require the development and submission of additional data. There also are continuing, annual program fees for any marketed products. Drug manufacturers and their subcontractors involved in the manufacture and distribution of approved drugs 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 cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements. Manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and other tracking requirements and must notify the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including AEs 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

studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences 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, warning letters or untitled letters;
- clinical holds on clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications or suspension or revocation of product approvals;
- product seizure or detention or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases, and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising, and promotion of drug products. A company can make only those claims relating to safety and efficacy, purity, and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising, and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labelling.

Other Healthcare Laws

In the United States, drug manufacturers and sponsors are subject to a number of federal and state healthcare regulatory laws that restrict business practices in the healthcare industry. These laws include, but are not limited to, federal and state anti-kickback, false claims, and other healthcare fraud and abuse laws, as follows:

The U.S. federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving, or providing any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering, or arranging for, or recommending the purchase, lease, or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid, or other federal healthcare programs. 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.

The federal false claims laws, including the civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or knowingly making a false statement to avoid, decrease, or conceal an obligation to pay money to the U.S. federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. Actions under the civil False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Moreover, a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

In addition, the civil monetary penalties statute, subject to certain exceptions, prohibits, among other things, the offer or transfer of remuneration, including waivers of copayments and deductible amounts (or any part thereof), to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or a state healthcare program.

HIPAA created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. 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 ("HITECH"), and their respective implementing regulations, which impose obligations on "covered entities," including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective "business associates" and their respective subcontractors that create, receive, maintain, or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services ("CMMS"), information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain other healthcare professionals including physician assistants and nurse practitioners, and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMMS ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations extend to include transfers of value made to certain non-physician providers (physician assistants, nurse practitioners, clinical nurse

specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified-nurse midwives).

There are federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, and such reported prices may be used in the calculation of reimbursement and/or discounts on approved products.

Similar state and local laws and regulations may also restrict business practices in the pharmaceutical industry, such as state anti-kickback and false claims laws, which may apply to business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by patients themselves; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing information and marketing expenditures or which require tracking gifts and other remuneration and items of value provided to physicians, other healthcare providers and entities; and state and local laws that require the registration of pharmaceutical sales representatives.

Violations of any of these laws and other applicable healthcare fraud and abuse laws may be punishable by criminal and civil sanctions, including fines and civil monetary penalties, the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid), disgorgement and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties, as well as imprisonment, also can be imposed upon executive officers and employees of such companies.

Coverage and Reimbursement

Sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. In the United States, no uniform policy exists for coverage and reimbursement for pharmaceutical products among third-party payors. Therefore, decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. The process for determining whether a third-party payor will provide coverage for a product typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved.

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 FDA-approved products for a particular indication, or place products at certain formulary levels that result in lower reimbursement levels and higher cost-sharing obligation imposed on patients. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, and they often require us to provide scientific and clinical support for the use of our products to each payor separately, which can be a time-consuming process, with no assurance that coverage and

adequate reimbursement will be applied consistently or obtained in the first instance. Additionally, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved.

Moreover, as a condition of participating in, and having products covered under, certain federal healthcare programs, such as Medicare and Medicaid, we are subject to federal laws and regulations that require pharmaceutical manufacturers to calculate and report certain price reporting metrics to the government, such as Medicaid Average Manufacturer Price ("AMP"), and Best Price, Medicare Average Sales Price, the 340B Ceiling Price and Non-Federal AMP reported to the Department of Veteran Affairs, and with respect to Medicaid, pay statutory rebates on utilization of manufacturers' products by Medicaid beneficiaries. Compliance with such laws and regulations require significant resources and any findings of non-compliance may have a material adverse effect on our revenues.

Healthcare Reform

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. In the United States, by way of example, in March 2010, the ACA was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States and significantly affected the pharmaceutical industry. The ACA, among other things, increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs; required collection of rebates for drugs paid by Medicaid managed care organizations; required manufacturers to participate in a coverage gap discount program, under which they must agree to offer point-of-sale discounts (increased to 70%, effective as of January 1, 2019) off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs; implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected expanded the types of entities eligible for the 340B drug discount program; expanded eligibility criteria for Medicaid programs; created 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 established a Center for Medicare Innovation at CMMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, administrative, executive and Congressional legislative challenges to certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. In December 2017, Congress repealed the tax penalty, effective January 1, 2019, for an individual's failure to maintain ACA-mandated health insurance as part of the Tax Act. President Biden issued an executive order that 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 possible that the ACA will be subject to judicial or Congressional challenges in the future. Further,

there have been a number of health reform initiatives by the Biden administration that have impacted the ACA. For example, on August 16, 2022, President Biden signed the IRA into law, which sets forth meaningful changes to drug product reimbursement by Medicare. Among other actions, the IRA permits HHS to engage in price-capped negotiation to set the price of certain drugs and biologics reimbursed under Medicare Part B and Part D. The IRA contains statutory exclusions to the negotiation program, including for certain orphan designated drugs for which the only approved indication (or indications) is for the orphan disease or condition. Should our product candidates be approved and covered by Medicare Part B or Part D, and fail to fall within a statutory exclusion, such as that for an orphan drug, those products could, after a period of time, be selected for negotiation and become subject to prices representing a significant discount from average prices to wholesalers and direct purchasers. The IRA also establishes a rebate obligation for drug manufacturers that increase prices of Medicare Part B and Part D covered drugs at a rate greater than the rate of inflation. The inflation rebates may require us to pay rebates if we increased the cost of a covered Medicare Part B or Part D approved product faster than the rate of inflation. In addition, the law eliminates the "donut hole" under Medicare Part D beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees' prescription costs for brand drugs below the out-of-pocket maximum and 20% once the out-of-pocket maximum has been reached. Our cost-sharing responsibility for any approved product covered by Medicare Part D could be significantly greater under the newly designed Part D benefit structure compared to the pre-IRA benefit design. Additionally, manufacturers that fail to comply with certain provisions of the IRA may be subject to penalties, including civil monetary penalties. The IRA is anticipated to have significant effects on the pharmaceutical industry and may reduce the prices we can charge and reimbursement we can receive for our products, among other effects. It is unclear how such challenges and the healthcare reform measures of the Biden administration will impact the ACA.

In addition, other federal health reform measures have been proposed and adopted in the United States since the ACA was enacted. For example, as a result of the Budget Control Act of 2011, providers are subject to Medicare payment reductions of 2% per fiscal year, which went into effect on April 1, 2013. This 2% reduction was temporarily suspended during the COVID-19 pandemic, but has since been reinstated and, unless Congress and/or the Executive Branch take additional action, will begin to increase gradually starting in April 2030, reaching 4% in April 2031, until sequestration ends in October 2031. Further, the American Taxpayer Relief Act of 2012 reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments from providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015 also introduced a quality payment program under which certain individual Medicare providers will be subject to certain incentives or penalties based on new program quality standards. In November 2019, CMS issued a final rule finalizing the changes to the Medicare Quality Payment Program.

There has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration

announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 30, 2020, HHS, finalized 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 IRA delayed the implementation of the rule to January 1, 2032. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers; the implementation of these provisions has also been delayed by the IRA until January 1, 2032. In addition, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate price cap, currently set at 100% of a drug's average manufacturer price for single source and innovator multiple source products, beginning on January 1, 2024. Further, in July 2021, the Biden Administration released an executive order that included multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug price reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions by HHS. No legislative or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of the budget reconciliation process. Additionally, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subjects drug manufacturers to civil monetary penalties and a potential excise tax for offering a price that is not equal to or less than the negotiated "maximum fair price" under the law, and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry.

Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical 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, mechanisms to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

We expect additional state and federal healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

Data Privacy and Security Laws

Numerous state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality and security of personal information,

including health-related information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, including HIPAA, and federal and state consumer protection laws and regulations (e.g., Section 5 of the Federal Trade Commission Act) that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, certain state and non-U.S. laws, such as the California Consumer Privacy Act ("CCPA"), the California Privacy Rights Act ("CPRA") and the GDPR, govern the privacy and security of personal information, including health-related information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations and other obligations are constantly evolving, may conflict with each other to make compliance efforts more challenging, and can result in investigations, proceedings, or actions that lead to significant penalties and restrictions on data processing.

Regulation and Procedures Governing Approval of Medicinal Products in the EU

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our product candidates to the extent we choose to sell any of our product candidates outside of the United States. Whether or not we obtain FDA approval for a product, we or our third-party partners must obtain approval of a product by equivalent competent authorities in foreign jurisdictions before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. As in the United States, post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution would apply to any product that is approved outside the United States.

The process governing the marketing authorization ("MA"), of medicinal products in the EU entails satisfactory completion of preclinical studies and adequate and well-controlled clinical trials to establish the safety, quality and efficacy of the medicinal product for each proposed therapeutic indication.

It also requires the submission to the relevant competent authorities of a marketing authorization application ("MAA") and granting of an MA by these authorities before the product can be marketed and sold in the EU.

The aforementioned EU rules are generally applicable in the European Economic Area ("EEA"), which consists of the 27 EU member states, as well as Norway, Liechtenstein and Iceland.

Failure to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, or with other applicable regulatory requirements may result in administrative, civil, or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant MA, product withdrawals and recalls, product seizures, suspension,

withdrawal, or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

EU Non-Clinical Studies and Clinical Trials

Similar to the United States, the various phases of non-clinical research in the EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical substances. Non-clinical health and environmental safety studies must be conducted in compliance with the principles of good laboratory practice ("GLP"), as set forth in Directive 2004/10/EC. In particular, non-clinical health and environmental safety studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Until recently, the Clinical Trials Directive 2001/20/EC, the Directive 2005/28/EC on GCP and the related national implementing provisions of the individual EU member states governed the system for the approval of clinical trials in the EU. As of January 31, 2022, the new Clinical Trials Regulation (EU) No 536/2014 ("the Regulation") took effect and replaced the Clinical Trials Directive 2001/20/EC. Commission Implementing Regulation (EU) 2017/556 replaces the GCP Directive 2005/28/EC. Pursuant to transitional provisions under the Regulation, trials for which a request for approval was submitted prior to January 31, 2022 may continue under the national implementations of the Directives for a period of up to three years. In addition, for a period of 18 months from January 31, 2022, sponsors may elect which process to follow.

The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the EU. The main characteristics of the regulation include: a streamlined application procedure via a single-entry point, the "EU portal"; 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 is assessed by the competent authorities of all EU member states in which an application for authorization of a clinical trial has been submitted (member states concerned). Part II is assessed separately by each member state concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU member state. However, overall related timelines are defined by the Clinical Trials Regulation.

Under either the Clinical Trials Directive or the Clinical Trials Regulation, clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Conference on Harmonization ("ICH"), guidelines on GCP, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative.

Under the Clinical Trials Directive, the sponsor was obliged to take out a clinical trial insurance policy and/or maintain an appropriate indemnity or compensation scheme for clinical trial subjects, and in most EU member states, the sponsor was liable to provide 'no fault' compensation to any study subject injured in the clinical trial. Similarly, the Clinical Trials Regulation prescribes that member states must implement a scheme providing for compensation for damage caused by participation in clinical trials within their territory in the form of insurance, a guarantee, or a similar arrangement that is equivalent as regards its purpose and which is appropriate to the nature and the extent of the risk.

Under the applicable regulatory system, an applicant must obtain prior approval from the competent national authority of the EU member states in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the competent ethics committee has issued a related favorable opinion. The application for authorization of a clinical trial must be accompanied by, among other documents, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation as prescribed by the Clinical Trials Regulation (EU) No 536/2014 and the Implementing Regulation (EU) 2017/556, as applicable, and further detailed in applicable guidance documents. Any substantial changes to the trial protocol or to other information submitted with the clinical trial application must be notified to or approved by the relevant competent national authorities and ethics committees. Medicinal products used in clinical trials must be manufactured in accordance with GMP.

EU Marketing Authorizations

To obtain an MA for a product in the EU, an applicant must submit a marketing authorization application ("MAA") either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in the EU member states (decentralized procedure, national procedure, or mutual recognition procedure). An MA may be granted only to an applicant established in the EU.

The centralized procedure comprises a single application, evaluation and authorization and provides for the grant of a single MA by the European Commission that is valid for all EU member states. Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) products designated as orphan medicinal products, (iii) advanced therapy medicinal products and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are a significant therapeutic, scientific or technical innovation or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the EMA's Committee for Medicinal Products for Human Use ("CHMP"), is responsible for conducting the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA.

Under the centralized procedure in the EU, 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 of the CHMP. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product targeting an unmet medical need is expected to be of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days (not including clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Unlike the centralized authorization procedure, the decentralized MA procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU member state in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU member states who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU member state cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the Heads of Medicines Agencies' Coordination Group for Mutual Recognition and Decentralised Procedures—Human for review. The subsequent decision of the European Commission is binding on all EU member states.

The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU member state to apply for this authorization to be recognized by the competent authorities in other EU member states. Like the decentralized procedure, the mutual recognition procedure is based on the acceptance by the competent authorities of the EU member states of the MA of a medicinal product by the competent authorities of other EU member states. The holder of a national MA may submit an application to the competent authority of an EU member state requesting that this authority recognize the MA delivered by the competent authority of another EU member state.

In principle, an MA has an initial validity of five years. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU member state in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with a consolidated version of the Common Technical Document, providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The European Commission or the competent authorities of the EU member states may decide, on justified grounds relating to pharmacovigilance, to proceed with one further five-year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (in case of centralized procedure) or on the market of the authorizing EU member state within three years after authorization ceases to be valid (the so-called sunset clause).

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines ("PRIME"), scheme, which provides incentives similar to the breakthrough therapy

designation in the United States. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that show the potential to target unmet medical needs. It permits increased interaction and early dialogue with companies developing promising medicinal products, to optimize their product development plans and speed up their evaluation to help the product reach patients as early as possible. Product developers that benefit from PRIME designation are potentially eligible for accelerated assessment of their MAA although this is not guaranteed. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

In the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once the specific obligations under the conditional MA are fulfilled (such as the completion of certain ongoing or new studies) and the complete data confirm that the medicinal product's benefits continue to outweigh its risks, the conditional MA can be converted into a traditional MA. However, if the specific obligations are not fulfilled within the timeframe set by the EMA, the MA will cease to be renewed.

An MA may also be granted "under exceptional circumstances" where the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information or when generating data may be contrary to generally accepted ethical principles. Like a conditional MA, an MA granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data on the medicinal product's efficacy and safety under normal conditions of use. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the MA is withdrawn in case the risk-benefit ratio is no longer favorable.

In addition to an MA, various other requirements apply to the manufacturing and placing on the EU market of medicinal products. Manufacture of medicinal products in the EU requires a manufacturing authorization, and import of medicinal products into the EU requires a manufacturing authorization allowing for import. The manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance. These requirements include compliance with EU GMP standards when manufacturing medicinal products and APIs, including the manufacture of APIs outside of the EU with the intention to import the APIs into the EU. Similarly, the distribution of medicinal products within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the EU member states. MA holders, manufacturing and import authorization (MIA) holders or distribution authorization holders may be subject to civil, criminal or administrative sanctions, including suspension of manufacturing authorization, in case of non-

compliance with the EU or EU member states' requirements applicable to the manufacturing of medicinal products.

EU Data and Market Exclusivity

The EU provides opportunities for data and market exclusivity related to MAs. Upon receiving an MA, innovative medicinal products are generally entitled to receive eight years of data exclusivity and ten years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial MA of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

In the EU, there is a special regime for biosimilars products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials regarding comparability must be provided in support of an application for MA.

EU Post-Approval Requirements

Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products.

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission or the competent regulatory authorities of the individual EU member states. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports ("PSURs").

All new MAAs must include a risk management plan describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU member states' laws governing promotion of medicinal products, interactions with physicians and other

healthcare professionals or organizations, misleading and comparative advertising and unfair commercial practices. Although these general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics ("SmPC"), as approved by the competent authorities in connection with an MA. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. Direct-to-consumer advertising of prescription medicinal products is also prohibited in the EU. There is also a prohibition on the offer or supply of inappropriate inducements to prescribe, subject to exemptions in certain jurisdictions, such as benefits that inexpensive and relevant to the practice of medicine.

Japanese Drug Regulation

Japan is a member of the ICH, and has pharmaceutical law and regulations that are similar in many respects those of the United States and the European Union. Those requirements are embodied in the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (also known as the Pharmaceuticals and Medical Devices Act) and related cabinet orders, Ministerial ordinances, and guidelines.

Clinical trials of medicinal products in Japan must be conducted in accordance with Japanese regulations and the ICH GCP. If the sponsor of the clinical trial is not an entity within Japan, it must appoint a domestic entity to act as its agent and carry out obligations on the overseas sponsor's behalf. The sponsor must hold a clinical trial insurance policy, and in accordance with industry practice, should establish a compensation policy for the injuries from the trial.

Prior to the commencement of human drug clinical trial, the sponsor must complete a pre-clinical safety evaluation of the investigative product and submit a clinical trial notification, including the clinical trial protocol, to the Ministry of Health Labor and Welfare's ("MHLW's") Pharmaceutical and Medical Device Agency ("PMDA"). This notification must be submitted after obtaining agreement of the investigational review board ("IRB") in relevant clinical trial institution(s). If the authorities do not raise an issue or comment on the notification application within 30 days, the sponsor may proceed to conclude clinical trial agreement(s) with the site(s) and commence the clinical trial. Any substantial changes to the trial protocol or other information submitted must be cleared by the IRB and notified to the authorities. Medicines used in clinical trials must be manufactured in accordance with Japan's good manufacturing practices ("GMP").

Non-clinical studies performed to demonstrate the safety of new chemical or biological substance must be conducted in compliance with the principles of Japanese Good Laboratory Practice rules ("GLP"), which reflect the Organization for Economic Co-operation and Development ("OECD") requirements. Currently, Japan and EU have a mutual recognition agreement for GLP, and data generated compliant with EU requirements will be accepted by the Japanese authorities. There is no similar agreement with the United States, but this is not a significant issue because of the OECD arrangement.

To market an innovative medicinal product in Japan, domestic or overseas applicant must obtain government approval (or marketing authorization) through a new drug application. If the product is designed for treating certain difficult diseases or those for which the patient population is limited, the applicant may be able to obtain designation as an orphan drug product if it demonstrates unique therapeutic value. There are also expedited programs for (i) truly innovative products with a unique mechanism of action and (ii) products which will satisfy unmet medical needs.

The evaluation of new drug applications is based on PMDA's assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. Once PMDA completes its review, the matter is considered by the advisory committee of experts, and the government grants approval upon any positive recommendation from the committee. If foreign data are part of the applicant, a dose response clinical trial for Japanese subjects may be required to ensure that data can be extrapolated to Japan's population.

Separate from the approval requirement, it is also mandatory that the marketing authorization holder or its partner in Japan possess a distribution license of an appropriate class to commercially distribute the product in Japan. Companies in Japan that actually manufacture drugs must possess a drug manufacturing license, and overseas manufacturers must obtain a manufacturing certification.

People's Republic of China ("PRC") Drug Regulation

China heavily regulates the development, approval, manufacturing, and distribution of drugs, including biologics. For purposes of the below description of drug regulation in China, Hong Kong, Macao and Taiwan, which are governed by separate laws, are excluded. The regulatory requirements applicable depend, in part, on whether the drug is made and finished in China, which is referred to as a domestically manufactured drug, or made abroad and imported into China in finished form, which is referred to as an imported drug, as well as the approval or "registration" category of the drug. For both imported and domestically manufactured drugs, China typically requires regulatory approval for a clinical trial application ("CTA") to conduct clinical trials in China and submit China clinical trial data, prior to submitting an application for marketing approval. For imported drugs, the sponsor and marketing authorization holder must be an overseas company that holds (or will hold) a marketing authorization in another country.

China also prioritizes review and approval of drugs and improvements to drugs (e.g., new indications, routes of administration) that have not yet been approved in any other jurisdiction (i.e., new to the world). In addition, China has created a set of expedited programs for drugs in high priority disease areas and drugs that more effectively treat life-threatening illnesses or that are needed for national emergencies.

The framework law in the drug space in China is the PRC Drug Administration Law ("DAL"). The DAL is implemented by various regulations and rules. The primary drug authority that regulates the life cycle of drugs is the NMPA. The NMPA has its own set of regulations further implementing the DAL. The regulation governing CTAs, marketing approval, and post-approval amendment and renewal is known as the Drug Registration Regulation ("DRR").

PRC Regulatory Authorities and Recent Government Reorganization

As noted above, NMPA is the drug regulatory agency that implements the laws, regulations, rules, and guidelines governing almost all of the key stages of the life-cycle of pharmaceutical products, including nonclinical studies, clinical trials, marketing approvals, manufacturing, advertising and promotion, distribution, and pharmacovigilance (i.e., post-marketing safety reporting obligations). NMPA's Center for Drug Evaluation ("CDE") approves clinical trials and conducts the technical evaluation of each drug and biologic marketing application to assess safety and efficacy. Provincial-level medical products administrations help to enforce these rules, and issue entity licenses to domestic companies, such as drug manufacturing and distribution licenses.

The National Health Commission of the PRC ("NHC") is China's primary healthcare regulatory agency. It is responsible for regulating the health care system, including the licensure of medical institutions, which also serve as clinical trial sites, and credentialing of medical personnel.

PRC Breakthrough Therapy Designation by the NMPA

Among other expedited programs, China administers a Breakthrough Therapy Designation. To qualify, a drug must be new to the world, intended to treat a life-threatening disease or one that can seriously impact quality of life, and for which there is no existing therapy in China or a demonstrated substantial improvement over available therapies. Drugs that are designated as breakthrough therapies will receive priority in meeting scheduling, enhanced guidance from CDE to expedite drug development, and may also qualify for other expedited programs, such as priority review and conditional approval.

PRC Non-Clinical Research

The NMPA requires preclinical data to support registration applications for imported and domestic drugs. For domestic laboratories, NMPA oversees an accreditation program pursuant to China's Good Laboratories Practice. If the pre-clinical research is conducted outside of China, then the applicant must sign and submit a certification with its CTA and marketing application stating that such research was conducted in accordance with applicable good laboratory practice rules.

PRC Clinical Trials and Regulatory Approval

Upon completion of preclinical studies, a sponsor will often need to conduct clinical trials in China to support registration. The materials required for a clinical trial application are substantial even at the CTA stage, including detailed manufacturing information. Drug registration trials in China many only be conducted after obtaining approval of a CTA submitted to CDE, approval of the ethics committee at each accredited hospital site, and human genetic resource approval ("HGR"), which is required for the collection of samples and associated data. CTAs may be approved in 60 business days if there is no comment from CDE, and the other applications can take approximately 3-4 months each. Information about clinical trials must be registered on an NMPA-administered platform and continually updated during the trial, and certain information, not including the protocol, is made publicly available on the platform.

PRC Trial Exemptions and Acceptance of Foreign Data

The NMPA may reduce requirements for clinical trials and data, depending on the drug and the existing data. In some cases, NMPA has granted waivers for all or part of trials and has stated that it will

accept data generated abroad (even if not part of a global study with a site in China), including early phase data, that meets its requirements. According to the Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data the data from foreign clinical trials must meet China's authenticity, completeness, accuracy, and traceability requirements, and be obtained consistent with the relevant requirements under the China's Drug GCP. Sponsors must be attentive to potentially meaningful ethnic differences in the subject populations.

PRC Clinical Trial Process and Good Clinical Practices

Pre-market drug clinical trials may have three phases, which may each require a CTA. These clinical trials must be conducted in accordance with a protocol that NMPA, various ethics committees at different sites, and the Office of HGR Administration all clear as part of the aforementioned approvals, and in accordance with applicable drug rules, including China's Drug GCP, issued jointly by NMPA and NHC. Trials must also be conducted at sites that have received credentials from the NHC and NMPA.

China is a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ("ICH"), so its GCP resemble the ICH GCP in a great many respects. However, there are some differences. For example, under China's GCP the sponsor must provide legal and economic guarantee to the investigator for clinical trial-related injuries, but harm or death caused by medical negligence is excluded. The drug rules contain procedures for amending the clinical trial approval, including obtaining approval for safety-related protocol amendments. NMPA (specifically, its Center for Food and Drug Inspections) has the power to audit trials for GCP compliance during and after the clinical trial.

PRC Drug Marketing Application and Approval

Upon completion of the development process, the applicant may submit a marketing authorization application to CDE. CDE will organize pharmaceutical, medical, and other technical personnel to conduct a review of the safety, efficacy, and quality controllability of the drug based on the application materials submitted, and the results of a verification and inspection (if required). If NMPA decides to approve the drug based on CDE's opinion, it will issue a drug registration certificate (i.e., a marketing authorization). A marketing authorization must be renewed every five years.

As the marketing authorization holder ("MAH"), a drug company is responsible for the life cycle of the product, including development, production and distribution, post-market studies, routine annual reporting, and the safety monitoring and reporting, among other obligations. The MAH may engage third parties to fulfill some of these obligations, such as appropriately-qualified manufacturers and distributors. If the MAH is overseas, as is required for imported drugs, the MAH must appoint an agent, which must be an entity in China that assists with meeting regulatory obligations. Marketing authorizations can be transferred to entities with the required capacity.

Both investigational and marketed drugs must be made in accordance with China GMPs. Domestic manufacturers must have a drug manufacturing license, and overseas manufacturers must certify that they will make drugs in accordance with GMP and meet their home country's requirements. Drugs must be distributed in China by licensed drug distributors.

Employees and Human Capital Resources

As of December 31, 2022, we had 13 full-time employees, consisting of clinical, research and development, business development, regulatory, finance and operational personnel, who are employed through our wholly owned subsidiary in the United States, NewAmsterdam Pharma Corporation. None of our employees are subject to a collective bargaining agreement. We consider our relationship with our employees to be good. We have also engaged consultants to assist with our clinical development and regulatory obligations. Our Dutch wholly owned subsidiary, NewAmsterdam Pharma B.V., had one full-time employee and engaged a total of nine independent contractors. These independent contractors provide a diverse array of services, which includes assisting with our clinical development and regulatory obligations.

NewAmsterdam Pharma Company N.V. had 3 full-time employees and zero independent contractors (*zelfstandigen zonder personeel*) as of December 31, 2022. No Works Council or other employee representative body (*personeelsvertegenwoordiging*) is established within NewAmsterdam Pharma Company N.V., NewAmsterdam Pharma Holding B.V. or NewAmsterdam Pharma B.V.

We recognize that our continued ability to attract, retain and motivate exceptional employees is vital to ensuring our long-term competitive advantage. Our employees are critical to our long-term success and are essential to helping us meet our goals. Among other things, we support and incentivize our employees in the following ways:

- Talent development, compensation and retention: We strive to provide our employees with a rewarding work environment, including the opportunity for growth, success and professional development. We provide a competitive compensation and benefits package, including bonus and equity incentive plans, a 401(k) plan—all designed to attract and retain a skilled and diverse workforce.
- Health and safety: We support the health and safety of our employees by providing comprehensive insurance benefits, company-paid holidays, a personal time-off program and other additional benefits which are intended to assist employees to manage their well-being.
- Inclusion and diversity: We are committed to efforts to increase diversity and foster an inclusive work environment that supports our workforce.

Legal Proceedings

From time to time, we may become involved in material legal proceedings or be subject to claims arising in the ordinary course of our business. We are currently not party to any legal proceedings material to our operations or of which any of our property is the subject, nor are we aware of any such proceedings that are contemplated by a government authority.

2.3 Organizational structure

As of December 31, 2022, we had four subsidiaries. The following table sets out for each of our subsidiaries, their countries of incorporation, and the percentage ownership and voting interest held by us (directly or indirectly through subsidiaries).

Company	Jurisdiction of Incorporation	Percentage Ownership and Voting Interest
NewAmsterdam Pharma B.V.	Netherlands	100%
NewAmsterdam Pharma Holding B.V.	Netherlands	100%
NewAmsterdam Pharma Corporation	U.S.	100%
Frazier Lifesciences Acquisition Corporation	U.S.	100%

2.4 Property, plants and equipment

We have our corporate headquarters at Gooimeer 2-35, 1411 DC, Naarden, the Netherlands, where we lease a small office space pursuant to a lease agreement entered into on July 3, 2020 which will continue until terminated by either us or the landlord upon one-month prior written notice. This facility houses our operations, human resources, information technology, finance, clinical operations and program management functions.

We also lease an administrative office of approximately 1,375 square feet, located at 20803 Biscayne Blvd., Suite #105, Aventura, FL 33180. This office space houses our U.S. administration, human resources, information technology, finance, clinical operations and program management functions.

We believe that these existing facilities will be adequate for our near-term needs. If required, we believe that suitable additional or alternative space would be available in the future on commercially reasonable terms. We are not aware of any environmental issues or other constraints that would materially impact the intended use of our facilities.

COVID-19 Impact on Facilities

We have implemented policies that enable our employees to work remotely, and such policies may continue for an indefinite period. We continue to evaluate our protocols and practices as the global response to the COVID-19 pandemic continues to evolve and continue to adhere to local, state and federal guidelines. While we are partially operating virtually in light of the COVID-19 pandemic, we believe our operational needs are being met for the time being. To date, we have not experienced any material impact on our ability to operate our business. We plan to periodically reassess the impact of COVID-19 on our facility needs.

2.5 Operating results

Results of Operations

Comparison of the Years Ended December 31, 2022 and December 31, 2021

The following table summarizes our consolidated statements of profit or loss for each period presented:

	For the year ended December 31,		
	2022	2021	Change
	(€ in thousands)		
Revenue	**97,500**	**—**	**97,500**
Research and development expenses	(82,230)	(25,032)	(57,198)
Selling, general and administrative expenses	(22,230)	(4,803)	(17,427)
Share listing expense	(60,600)	—	(60,600)
Total operating expenses	**(165,060)**	**(29,835)**	**(135,225)**
Finance income	11	9	2
Finance expense	(271)	(216)	(55)
Fair value change - earnout and warrants	(976)	—	(976)
Foreign exchange gains/(losses)	(9,256)	1,443	(10,699)
Loss before tax	**(78,052)**	**(28,599)**	**(49,453)**
Income tax expense	—	—	—
Total comprehensive loss for the period, net of tax	**(78,052)**	**(28,599)**	**(49,453)**

Revenue

Revenue increased by €97.5 million, from nil for the year ended December 31, 2021 to €97.5 million for the year ended December 31, 2022. This was driven by the revenue allocated to the license performance obligation out of the €115.0 million upfront payment received pursuant to the Menarini License on June 23, 2022. €21.5 million was allocated to the Research & Development performance obligation and recorded as deferred revenue. Of this amount, €4.0 million was recognized in respect of the Research and Development performance obligation for the period ended December 31, 2022.

Research and Development Expenses

Research and development expenses increased by €57.2 million, or 228%, from €25.0 million for the year ended December 31, 2021 to €82.2 million for the year ended December 31, 2022. This was largely driven by an increase of €46.0 million in clinical research and development costs, which related to costs incurred in connection with our larger Phase 3 clinical trials in 2022 compared to our smaller Phase 2 clinical trials which were mostly conducted in 2021.

Non-clinical expenses increased by €1.8 million, primarily as a result of costs incurred by the rat and hamster carcinogenicity study which is being conducted over two years and commenced at the end of 2021.

Personnel expenses related to research and development expenses increased by €3.4 million, primarily driven by our share-based compensation arrangements due to new grants awarded in 2022, as well as driven by the growth of our organization related to clinical trial management.

Manufacturing costs increased by €6.5 million as a result of our Phase 2 clinical trials that continued in 2022 in addition to startup API campaign, process optimization and validation, and kit, labeling and distribution costs for our two lipid and CVOT Phase 3 clinical trials.

Regulatory expenses and other research and development ("R&D") costs did not materially fluctuate between the years ended December 31, 2022 and 2021.

The following table summarizes our research and development expenses for the periods indicated:

	For the year ended December 31,		
	2022	2021	Change
	(€ in thousands)		
Clinical expenses	(56,795)	(10,842)	(45,953)
Non-clinical expenses	(2,802)	(974)	(1,828)
Personnel expenses	(6,752)	(3,363)	(3,389)
Manufacturing costs	(14,850)	(8,338)	(6,512)
Regulatory expenses	(901)	(1,452)	551
Other R&D costs	(130)	(63)	(67)
Total research and development expenses	**(82,230)**	**(25,032)**	**(57,198)**

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by €17.4 million, or 363%, from €4.8 million for the year ended December 31, 2021 to €22.2 million for the year ended December 31, 2022. This increase was primarily driven by a:

- €3.3 million increase in personnel expenses related to selling, general and administrative expenses due to increased fees, hiring of individuals involved with administrative and quality control activities and share-based payments due to new grants awarded in 2022;
- €0.6 million and €1.4 million increases in intellectual property and other legal costs, respectively, due to increased efforts related to drug patent development and global patent protection efforts, legal services rendered with respect to due diligence and the Business Combination; and
- €4.9 million increase in finance and administration costs due to increased audit fees and accounting and advisory fees in support of the Menarini License and Business Combination.

Additionally, new expenses incurred in 2022 include €3.0 million in transaction costs related to the Business Combination and commission expense totaling €2.5 million as part of the Menarini License.

Other increases include €0.8 million in marketing and communication costs related to business development and initial commercialization activities and €0.9 million in facility-related and other costs largely related to an increase in insurance costs due to an increase in coverage for directors and officers.

The following table summarizes our selling, general and administrative expenses for the periods indicated:

	For the year ended December 31,		
	2022	2021	Change
	(€ in thousands)		
Personnel expense	(5,017)	(1,754)	(3,263)
Intellectual property	(1,348)	(708)	(640)
Legal costs	(2,176)	(799)	(1,377)
Finance and administration	(5,209)	(270)	(4,939)
Transaction costs	(3,021)	—	(3,021)
Marketing and communication	(1,663)	(845)	(818)
Commission expense	(2,485)	—	(2,485)
Facility-related and other costs	(1,311)	(427)	(884)
Total selling, general and administrative expenses	**(22,230)**	**(4,803)**	**(17,427)**

Share Listing Expense

Share listing expenses increased from nil in the year ended December 31, 2021 to €60.6 million for the year ended December 31, 2022 due to the Business Combination and represents the difference between the fair value of the net assets contributed by FLAC and the fair value of equity instruments provided to former FLAC shareholders. Share listing expense results from the Business Combination being within the scope of IFRS 2 and represents the excess of the fair value of the equity instruments issued over the fair value of the identified net assets contributed.

Finance Expense

Finance expense increased by €55 thousand, from €0.2 million for the year ended December 31, 2021 to €0.3 million for the year ended December 31, 2022. This increase was largely driven by the negative interest charged on cash balances and an increase in interest on lease liabilities.

Fair Value Change - Earnout and Warrants

Fair value change - earnout and warrants increased by €1.0 million, from nil for the year ended December 31, 2021 to €1.0 million for the year ended December 31, 2022. This increase was largely driven by the change in fair values of the derivative warrant liabilities and the derivative earnout liabilities between the Closing Date and year-end, with the liabilities resulting from the Business Combination.

Foreign Exchange Gains/(Losses)

Net foreign exchange gains/(losses) decreased by €10.7 million, from a gain of €1.4 million for the year ended December 31, 2021 to a loss of €9.3 million for the year ended December 31, 2022. This was largely driven by the effect of the appreciation of the U.S. Dollar on cash balances held in U.S. Dollars at the end of the year and the increased research and development expenditures denominated in U.S. Dollars.

Income Tax

We recorded no income tax expense for both the year ended December 31, 2021 and 2022. We

have a history of losses and therefore pay no corporate tax. We have not recognized deferred tax assets relating to losses carried forward as we have no products approved for sale, and it is not probable that the loss carryforwards will be utilized.

Loss for the Year

Loss for the year increased by €49.5 million, from a loss of €28.6 million for the year ended December 31, 2021 to a loss of €78.1 million for the year ended December 31, 2022, mainly driven by the increase in research and development expenses and share listing expense, offset by €97.5 million in revenue that was recognized pursuant to the Menarini License.

LIQUIDITY AND CAPITAL RESOURCES

We are a clinical-stage biopharmaceutical company and, since inception, we have incurred significant operating losses and expect to continue to do so for the foreseeable future. Since inception, we have not generated any product revenues or net positive cash flows from operating activities. We will not receive any product revenues or net positive cash flows from operating activities until we successfully develop a product candidate, obtain regulatory approval, and successfully commercialize it.

To date, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, undertaking preclinical studies and conducting clinical trials of obicetrapib. As a result, we are not yet profitable and have incurred losses in each annual period since our inception. As at December 31, 2022, we had an accumulated loss of €119.4 million. We expect to continue to incur significant losses for the foreseeable future. We anticipate that our expenses will increase substantially as a result of:

- the progress and costs of our discovery, preclinical and non-clinical development;
- the progress and costs of our clinical trials, including costs related to clinical sites, clinical investigators and CROs that are assisting with our sponsored clinical trials, and other research and development activities;
- the costs and timing of obtaining regulatory approval, including the expenses of filing NDAs and MAAs, and the related expenses involved in validating our manufacturing processes;
- the costs associated with any future investigator-sponsored preclinical studies and clinical trials;
- the costs of filing, prosecuting, defending and enforcing any patent applications, claims, patents and other intellectual property rights;
- the costs and timing of obtaining sufficient quantities of our product candidate for clinical trials by establishing production capacities through contracts with contract manufacturing organizations ("CMOs");
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the potential costs of any delays caused by the COVID-19 pandemic and associated restrictions;
- the costs of preparing for launch and commercialization of our product candidate; and
- the costs of operating as a public company in the United States.

We may encounter unforeseen expenses, difficulties, complications, delays and other factors that may adversely affect our business. The magnitude of our future net losses will depend on the rate of future growth of our expenses combined with our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our shareholders' equity and working capital unless and until eliminated by revenue generation and growth.

We have historically funded our operations primarily through private placements of shares, the sale of convertible notes and the proceeds from the Business Combination. As at December 31, 2022, we had cash of €438.5 million. Based on our current operating plan, we believe that our existing cash, including the upfront payment of €115 million received from the Menarini License in July 2022, will be sufficient to fund our anticipated level of operations through 2026. We may consider raising additional capital to pursue strategic investments, to take advantage of financing opportunities or for other reasons. Until we can generate substantial product revenues, if ever, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, convertible loans, warrants, collaborations, or other means. We may consider raising additional capital to take advantage of favorable market conditions or for other strategic considerations even if we have sufficient funds for planned operations. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or privately placed equity offerings of securities, the terms of these securities or offerings may include liquidation or other preferences that adversely affect our other shareholders' rights. To the extent that we raise additional funds by issuing and selling equity or equity-linked securities, shareholders will experience dilution. If we raise additional capital through debt financing, we would likely be subject to fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, licensing or selling assets, making capital expenditures or declaring dividends. Capital may become difficult or impossible to obtain due to poor market or other conditions outside of our control. If we are unable to raise sufficient additional funds on favorable terms as and when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to others any of our potential future product candidates that we would prefer to develop and commercialize ourselves. See the section of this report entitled "*3.2 Risk factors*" for additional detail regarding these risks.

We plan to utilize our existing cash and other financial assets on hand primarily to fund our research and development initiatives to continue or commence clinical trials and seek regulatory approval for obicetrapib. We also expect to make capital expenditures to support our anticipated growth. Cash in excess of immediate requirements is invested in accordance with our investment policy which has the primary purpose of capital preservation and liquidity.

Cash Flows

Comparison of cash flows for the years ended December 31, 2022 and 2021

The following table summarizes our cash flows for each period presented:

	For the year ended December 31,		
	2022	**2021**	**Change**
	(€ in thousands)		
Net cash flows provided by/(used in) operating activities	7,972	(25,164)	33,136
Net cash flows provided by/(used in) investing activities	715	(20)	735
Net cash flows provided by financing activities	375,177	68,990	306,187
Foreign exchange differences	1,566	1,425	141
Cash at the beginning of the year	53,092	7,861	45,231
Cash at the end of the year	**438,522**	**53,092**	**385,430**

Net Cash Flows from Operating Activities

During the year ended December 31, 2022, net cash provided by operating activities was €8.0 million, largely driven by research and development expenses incurred as a result of spending related to the initiation of our Phase 3 clinical trials and selling, general and administrative expenses incurred as a result of activities related to the Business Combination and Menarini License, offset by the upfront fee received pursuant to the Menarini License. See "2.5 *Operating Results—Results of Operations*" for more information.

During the year ended December 31, 2021, net cash used in operating activities was €25.2 million, largely driven by the loss before tax of €28.6 million and changes in prepayments and other receivables of €4.4 million, largely driven by an increase in a value added tax receivable. This was partially offset by changes in trade and other payables of €8.2 million driven by the increase in clinical trials and chemistry, manufacturing and controls activities which drove an increase in payables to CROs and CMOs, and by an increase in a value added tax payable of €2.8 million.

Net Cash Flows from Investing Activities

During the year ended December 31, 2022, net cash provided by investing activities was €715 thousand driven by the purchase of equipment and repayment of loan receivable. During the year ended December 31, 2021, net cash used in investing activities was €20.0 thousand driven by the purchase of equipment.

Net Cash Flows from Financing Activities

During the year ended December 31, 2022, net cash provided by financing activities was €375.2 million driven by the Business Combination and the second tranche of the Series A Financing. During the year ended December 31, 2021, net cash provided by financing activities was €69.0 million driven by proceeds from the issuance of shares and capital contributions of €69.0 million.

Contractual Obligations and Commitments

Third-Party Service Agreements

We have entered into a variety of agreements and financial commitments in the normal course of business with CROs, CMOs, and other third parties for preclinical and clinical development and manufacturing services. The terms generally provide us with the option to cancel, reschedule and adjust our requirements based on our business needs, prior to the delivery of goods or performance of services. Payments due upon cancellation generally consist only of payments for services provided or expenses incurred, including non-cancelable obligations of our service providers, up to the date of cancellation. However, some of our service providers also charge cancellation fees upon cancellation. The amount and timing of such payments are not known, but at December 31, 2022 they are estimated to be a maximum of €16.6 million due within one year and €5.1 million due in more than a year.

Leases

We are party to two lease agreements, the Naarden Lease and the office lease agreement with Renaissance Aventura LLC, dated May 24, 2021 (the "Miami Lease"). Under the Naarden Lease, we are obligated to pay €40 thousand per year in rent. The Naarden Lease will continue until terminated by either us or the landlord. Pursuant to the Miami Lease, we are required to pay annual rent ranging from $69 thousand to $75 thousand, increase from the low end of the range to the higher end of the range for each year of the lease. The Miami Lease will expire by its terms on October 31, 2024, unless terminated earlier by either party pursuant to the terms of the Miami Lease.

2020 SPA and Profit Right Agreement

On April 9, 2020, we entered into a share sale and purchase agreement with Amgen (the "2020 SPA"), to purchase all of the outstanding share capital of Dezima Pharma B.V. ("Dezima"), a company whose principal activity was to develop compounds that treat cardiovascular disease related to dyslipidemia. The principal reason for this acquisition was to secure rights to intellectual property and know-how related to the patented drug obicetrapib and the in-process research and development. We paid cash consideration of €1 for the share capital of Dezima and agreed to make additional contingent payments to Amgen upon the potential occurrence of certain future events (if they occur) as further described below. In connection with the 2020 SPA, we entered into a profit right and waiver agreement with MTPC (the "Profit Right Agreement") in consideration for the waiver of certain historical intellectual property rights and related payment rights held by MTPC.

The two events that would have triggered the payment of additional consideration to Amgen and MTPC were a traditional underwritten initial public offering ("IPO") or an exit event, as defined in the 2020 SPA and the Profit Right Agreement. An exit event included a change of control transaction or the transfer of more than 50 percent of our then-outstanding shares. Under the 2020 SPA and the Profit Right Agreement, the aggregate contingent consideration to be paid to Amgen and MTPC resulting from the profit right and IPO share right is calculated as 17.63% of the proceeds, or an aggregate number of shares valued at the IPO price equal to 17.63% of the pre-public offering valuation if an IPO takes place, as applicable. Upon receiving notice of NewAmsterdam Pharma's intention to pursue an IPO, Amgen would have the right to repurchase all of the outstanding shares of Dezima at a certain specified price.

In addition, Amgen and MTPC were granted rights to match the terms offered by third parties in

connection with certain major corporate transactions involving NewAmsterdam Pharma. The Business Combination qualified as an exit event pursuant to both the 2020 SPA and the Profit Right Agreement. As a result, in connection with the Business Combination and pursuant to side letters entered into by the parties, Amgen and MTPC each received their respective profit right payments in the form of Ordinary Shares, as follows (for the avoidance of doubt, references below to shares on a "fully diluted basis" assume the exercise of all NewAmsterdam Pharma options outstanding immediately prior to the Exchange and are made after giving effect to the issuance of Ordinary Shares to MTPC and Amgen described below):

(a) shortly after the Exchange, and prior to the consummation of the Business Combination, a number of Ordinary Shares, in the aggregate, equal to (i) 17.63% of the number of shares of NewAmsterdam Pharma outstanding immediately prior to the consummation of the Exchange on a fully diluted basis, multiplied by (ii) the exchange rate applicable to all of holders of NewAmsterdam Pharma shares in the Exchange and then (iii) rounded to the nearest whole number where an entitlement to five-tenths (0.5) of an Ordinary Share shall be rounded up; and

(b) if and when the relevant development milestone is achieved, as soon as practicable thereafter, a number of Ordinary Shares, in the aggregate, equal to (i) 17.63% of the number of Earnout Shares on a fully diluted basis and then (ii) rounded to the nearest whole number where an entitlement to five-tenths (0.5) of an Ordinary Share shall be rounded up.

The payments to Amgen and MTPC described in clauses (a) and (b) above are referred to collectively as the "2020 Profit Rights." Upon receipt of the 2020 Profit Rights (but in the case of the Earnout Shares, only if the certain clinical development milestone is achieved during the Earnout Period), all rights of Amgen and MTPC under the 2020 SPA and the Profit Right Agreement, respectively, were extinguished.

Menarini License

We will be responsible for the development and commercialization costs related to Licensed Products other than those in the Menarini Territory. In addition, under specified conditions of the agreement, we agreed to bear 50% of certain development costs incurred by the other party in the development of the Licensed Products in the Menarini Territory. Please see "*—Liquidity and Capital Resources*" above for a description of the Menarini License.

RESEARCH AND DEVELOPMENT, PATENTS AND LICENSES, ETC.

See "2.2 *Overview*" and "2.5 *Operating results*."

TREND INFORMATION

See "2.5 *Operating results*."

CRITICAL ACCOUNTING ESTIMATES

We refer to "Note 3 - Use of Judgments and Estimates" to our consolidated financial statements included elsewhere in this report.

2.6 Material subsequent events

The Company evaluated subsequent events for recognition or disclosure through March 31, 2023, the date these consolidated financial statements were authorized for issuance by the Board.

On January 1, 2023, the Company granted options to purchase an aggregate of 4,171,572 Ordinary Shares to certain employees and directors. Such options each have an expiration date of ten years from the date of grant and an exercise price of $10.90.

On January 14, 2023, the Company granted options to purchase an aggregate of 18,600 Ordinary Shares to a non-executive director. Such options each have an expiration date of ten years from the date of grant and an exercise price of $10.22.

In January 2023, the Group achieved a clinical success milestone related to our Phase 2b ROSE2 clinical trial and as a result expect received a milestone payment from Menarini in April 2023 amounting to €5 million.

The Company announced on March 3, 2023 that David Topper, Chief Financial Officer, who provided advice and guidance in support of the Company's now complete public company transition, has resigned. The Company has appointed current Chief Accounting Officer, Louise Kooij, as Interim Chief Financial Officer. The Company intends to conduct a search for a new permanent chief financial officer.

See Note 26 (*Events After the Reporting Period*) to the Consolidated Financial Statements included in chapter 4.1 of this report for an overview of events which do not need to be discussed in the Company's statutory annual accounts and which might influence the Company's outlook.

3 RISKS ASSOCIATED WITH OUR BUSINESS

3.1 Introduction

Drug development is inherently risky. There is no certainty that Obicetrapib will progress successfully through development, obtain regulatory approval and become a marketable product. The Company's internal development expertise and knowledge of the respective disease areas should, however, allow it to develop its products in a manner that will substantially reduce, but which cannot eliminate, these risks in the future. As a pre-revenue, clinical-stage company, we face a number of risks including those related to our financing needs, our drug development program and related regulatory regime, our intellectual property and other risks applicable associated with owning our publicly traded shares. A complete description of the risks applicable to our business can be found under the heading "*Item 3. D. Risk Factors*" in our annual report on Form 20-F filed with the Securities and Exchange Commission on March 31, 2023.

The Company's activities involve an ongoing assessment of risks and the Company seeks to mitigate such risks where possible. The Board has undertaken an assessment of the principal risks and uncertainties facing the Company, including those that would threaten its business model, future performance, solvency and liquidity. In addition, the Board has considered the longer-term viability of the Company including factors such as the prospects of the Company and its ability to continue in operation for the foreseeable future. The Board considers that the disclosures outlined in this report are

appropriate given the stage of development of the business.

3.2 General description of our risk appetite

Our risk appetite serves as a guideline to determine the measures we may take in mitigating some of the risks and uncertainties we face. Our risk appetite is aligned with our strategy and priorities. The business we operate in is inherently high-risk. In general, we are willing, and in our view required, to take significant risks to be able to operate successfully in our line of business. Some of the risks and uncertainties we face are entirely outside of our control whereas others may be influenced or mitigated.

The process of developing, implementing and improving risk management procedures remains an ongoing effort. In accordance with guideline 400.110c of the Dutch Counsel for annual reporting (Raad voor de Jaarverslaggeving), this risk management section provides an overview of the key risks, including risk mitigating actions taken or planned to be taken by us. The mentioning of these mitigating actions may not in any way be viewed as an implied or express guarantee that such mitigation will in practice be effective in limiting the risk exposure and/or the potential damage to us from any such risk materializing.

3.3 Risk factors and mitigating actions taken

Risk related to	Risk area	Expected impact on materialization	Risk appetite / mitigation action
Development and regulatory approval of our lead candidate	The Company is dependent on the success of its only product candidate, obicetrapib, and cannot guarantee that obicetrapib will successfully complete clinical development, receive regulatory approval or, if approved, be successfully commercialized. The regulatory approval process of the FDA, the EMA, the MHRA, and comparable regulatory authorities are lengthy, time-consuming and inherently unpredictable, and if we are delayed in obtaining or are ultimately unable to obtain regulatory approval for any of the Company's product candidates, its business will be substantially harmed.	The Company's future success, including its ability to generate revenue, depends on its ability to develop, commercialize, market and sell obicetrapib. However, obicetrapib has yet to receive marketing approval from the FDA, the EMA or other comparable regulatory authorities. The Company currently generates no revenue from the sale of any products, and it may never be able to develop or commercialize a marketable product. Failure to comply with regulatory	In addition to the safety and efficacy traits of any product candidate, clinical trial failures may result from a multitude of factors including flaws in trial design, dose selection, placebo effect and patient enrollment criteria which the Company is not currently aware of. Although the Company monitors the regulatory landscape and engages with the authorities when it deems that necessary, this is an inherent risk in biotech drug development and therefore has limited mitigation abilities.

		requirements may result in, among other things, delays, suspension, restrictions on marketing activities, fines, refusals by regulators to approve product candidates and withdrawal of approvals as well as fines.	
Dependence on Menarini	The Company relies on its collaboration with Menarini for the commercialization of the product in certain European areas.	Failure of Menarini to fulfill all or part of its obligations to us under the agreement, a breakdown of collaboration between parties or a complete or partial loss of this relationship, could materially harm our business if the product is approved in the relevant jurisdictions.	Together with Menarini, the Company has created a governance structure in which all activities are monitored and discussed on a regular basis.
Intellectual property	Our future commercial success depends, in part, on our ability to obtain and maintain patent and other proprietary protection for commercially important inventions, to obtain and maintain know-how related to our business, including our product candidate, to defend and enforce our intellectual property rights, in particular our patent rights, to preserve the confidentiality of our trade secrets, and to operate without infringing, misappropriating, or violating the valid and enforceable patents and other intellectual property rights of third parties.	If our efforts to obtain, protect or enforce our patents and other intellectual property rights related to our product candidate and technologies are not adequate, including due to the risk that we are unaware of prior art that may affect the validity of our patents, we may not be able to compete effectively in our market and we otherwise may be harmed.	We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

Commercialization of our product candidates	Obicetrapib, if approved, will face significant competition from competing therapies and our failure to compete effectively may prevent us from achieving significant market penetration.	The Company's competitors may succeed in developing, acquiring or licensing on an exclusive basis products that are more effective or less costly than the Company's product candidate which may adversely effect the Company's business.	Competition is an inherent risk for any industry including drug development. Through our IP strategy, we attempt to have data exclusivity for our products. Development in other companies is essentially out of our control but we monitor the competitive landscape and incorporate that into our business strategy.
Reimbursement from third-party payors	It may be difficult for the Company to profitably sell obicetrapib or any future product candidate in the United States, if approved, if coverage and reimbursement for these products is limited by government authorities and/or third-party payor policies.	Market acceptance and sales of obicetrapib and other product candidates, if approved, will depend on the coverage and reimbursement policies of government authorities and third-party payors, in addition to any healthcare reform measures that may affect reimbursement. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will cover and establish reimbursement and co-payment levels.	The ability of third-party financing is dependent on external factors and is therefore not entirely in the Company's control. The Company monitors the market conditions for opportunities to seek reimbursement.
Operational activities	The Company relies, and expects to continue relying, on third parties and consultants to assist it in conducting the Company's clinical trials, including its Phase 3 clinical trials for	If the Company's CROs or any other third parties upon which the Company relies on for administration and conduct of its	The Company reviews and monitors the activities of third parties. These include setting contractual deliverables, quality assurance audits and

	obicetrapib. If these third parties or consultants do not successfully carry out their contractual duties or meet expected deadlines, the Company may be unable to obtain regulatory approval for or commercialize obicetrapib, if approved.	clinical trials 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 the clinical protocols, regulatory requirements, or for other reasons, or if they otherwise perform in a substandard manner, the Company's clinical trials may be extended, delayed, suspended or terminated, and the Company may not be able to complete development of, obtain regulatory approval for, or successfully commercialize obicetrapib.	performance reports, among other activities.
Capital needs	The Company is a clinical stage biopharmaceutical company with limited operating history, no approved products and no historical product revenues, which makes it difficult to assess its future prospects and financial results. The Company has incurred losses since inception and that expects to incur losses for the foreseeable future.	The Company will need substantial additional financing to achieve its goals, and a failure to obtain this capital when needed and on acceptable terms, or at all, could force it to delay, limit, reduce or terminate product development, commercialization efforts or other operations.	The Company maintains an efficient and disciplined cash management and cash forecasting process to identify potential future funding requirements in order to timely raise sufficient capital.
Financial position	Th Company's ability to use its tax losses to offset future	The Company's ability to utilize tax losses and tax loss	The Company continuously monitors changes in tax laws to

	taxable income may be subject to certain limitations.	carryforwards is conditioned upon it attaining profitability and generating taxable income. The Company has incurred significant tax losses since inception and it is anticipated that it will continue to incur significant losses.	implement the most efficient tax planning strategy. Our profitability is directly linked to the development and regulatory approval of Obicetrapib.
The Russian invasion of Ukraine	On 24 February 2022, the conflict between Russia and Ukraine escalated. As a result, a number of countries have and continue to impose new sanctions against Russian government entities, state-owned enterprises and certain specified entities and individuals linked to Russia anywhere in the world. Sanctions have also been imposed on Belarus.	Uncertainty and instability resulting from the conflict between Russia and Ukraine could negatively impact our business operations and disrupt our supply chain.	The Company continues to monitor the situation to be able to take action if needed.
Outbreaks of pandemics	The COVID-19 pandemic, and any future pandemics, may adversely affect our business and that of our suppliers, CROs or other third parties relevant to our business.	Further outbreaks and preventative or protective actions that governments, corporations or individuals may take in the future to contain the spread of COVID-19 or future outbreaks may result in reduced operations, delays in the start of clinical trials or other research and development efforts, business disruption for the Company and its suppliers, CROs and other third parties with which the Company does business, and potential delays or disruptions related to regulatory approvals.	The Company together with its partners have put into place actions to minimize the impact from the virus outbreak.

The above risks have not materialized during the period ended on December 31, 2022. The Company's activities are also exposed to market risk (interest rate risk and foreign currency risk), credit risk and liquidity risk. The Company has a cash management policy in place to minimize potential adverse effects. The risk factors included above represent a summary of the risks applicable to the Company's business. More information around these risks has been disclosed in note 16 to the consolidated financial statements as well as section "Iteem 3. D. Risk Factors" in the Company's Form 20-F filed with the SEC for the year ended December 31, 2022.

4 FINANCIAL STATEMENTS

4.1 Consolidated Financial Statements

CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND COMPREHENSIVE LOSS

	Note	For the year ended December 31, 2022	2021
(In thousands of Euro, except per share amounts)			
Revenue	5	**97,500**	**—**
Research and development expenses	6	(82,230)	(25,032)
Selling, general and administrative expenses	7	(22,230)	(4,803)
Share listing expense	9	(60,600)	—
Total operating expenses		**(165,060)**	**(29,835)**
Operating loss		**(67,560)**	**(29,835)**
Finance income	14	11	9
Finance expense	22	(271)	(216)
Fair value change – earnout and warrants	17	(976)	—
Foreign exchange gains/(losses)	16	(9,256)	1,443
Loss before tax		**(78,052)**	**(28,599)**
Income tax expense	12	—	—
Loss for the year		**(78,052)**	**(28,599)**
Other comprehensive loss, net of tax		—	—
Total comprehensive loss for the year, net of tax		**(78,052)**	**(28,599)**
Net loss per share (in Euro)	21		
Basic and diluted*		€ (0.96)	€ (1.19)

(*) Restated - see Note 21

The accompanying notes are an integral part of these consolidated financial statements.

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	Note	As at December 31, 2022	2021
(In thousands of Euro)			
Assets			
Non-current assets			
Intangible assets	15	83,160	—
Property, plant and equipment	13	144	190
Loan receivable	14	—	718
Long term prepaid expenses	5	146	—
Total non-current assets		**83,450**	**908**
Current assets			
Prepayments and other receivables	10	9,611	5,782
Cash	18	438,522	53,092
Total current assets		**448,133**	**58,874**
Total assets		**531,583**	**59,782**
Equity and liabilities			
Equity			
Share capital	19	599,191	83,876
Other reserves	20	4,691	591
Accumulated loss		(119,361)	(34,676)
Total equity		**484,521**	**49,791**
Non-current liabilities			
Deferred revenue	5	4,492	—
Lease liability	22	56	111
Derivative earnout liability	17	7,053	—
Total non-current liabilities		**11,601**	**111**
Current liabilities			
Trade and other payables	11	18,503	9,827
Deferred revenue	5	13,008	—
Lease liability	22	62	53
Derivative warrant liabilities	17	3,888	—
Total current liabilities		**35,461**	**9,880**
Total equity and liabilities		**531,583**	**59,782**

The accompanying notes are an integral part of these consolidated financial statements.

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	Note	Issued capital	Share premium	Other reserves	Retained earnings	Total equity
(In thousands of Euro)						
Opening balance at January 1, 2021		**50**	**2,450**	**—**	**(6,077)**	**(3,577)**
Conversion of convertible debt	19	11	11,656	—	—	11,667
Series A - Tranche I	19	49	68,951	—	—	69,000
Issuance of non-voting shares	19	3	706	—	—	709
Share-based compensation		—	—	591	—	591
Total profit or loss and comprehensive loss for the year		—	—	—	(28,599)	(28,599)
As at December 31, 2021		**113**	**83,763**	**591**	**(34,676)**	**49,791**
Opening balance at January 1, 2022		**113**	**83,763**	**591**	**(34,676)**	**49,791**
Equity contribution (Series A - Tranche II)	19	57	79,623	—	—	79,680
Elimination of old shares (NewAmsterdam Pharma shareholders)	19	(170)	(163,386)	—	—	(163,556)
Equity contribution (NewAmsterdam Pharma shareholders)	19	4,351	159,205	—	—	163,556
Equity contribution (FLAC shareholders)	19	1,582	125,084	—	—	126,666
Equity contribution (PIPE Financing)	19	2,815	225,528	—	—	228,343
Equity contribution (Amgen & MTPC shareholders)	19	1,039	82,121	—	—	83,160
Transaction costs on issue of shares	19	—	(2,534)	—	—	(2,534)
Earnout obligation upon Closing (NewAmsterdam Pharma shareholders)	17	—	—	—	(6,633)	(6,633)
Share-based compensation	20	—	—	4,100	—	4,100
Total profit or loss and comprehensive loss for the year		—	—	—	(78,052)	(78,052)
As at December 31, 2022		**9,787**	**589,404**	**4,691**	**(119,361)**	**484,521**

The accompanying notes are an integral part of these consolidated financial statements.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Note	For the year ended December 31, 2022	2021
(In thousands of Euro)			
Operating activities:			
Loss before tax		(78,052)	(28,599)
Non-cash adjustments to reconcile loss before tax to net cash flows:			
Depreciation and amortization	13,22	72	14
Share listing expense	9	60,600	—
Finance income	14	(11)	(9)
Finance expense	22	9	2
Fair value change - derivative earnout and warrants	17	976	—
Foreign exchange gains/(losses)	16	9,256	(1,443)
Share-based compensation	20	3,922	1,049
Changes in working capital:			
Changes in prepayments and other receivables		(3,975)	(4,424)
Changes in trade and other payables		(2,063)	8,246
Changes in deferred revenue		17,500	—
Interest paid		(262)	—
Net cash provided by/(used in) operating activities		**7,972**	**(25,164)**
Investing activities:			
Purchase of equipment	13	(13)	(20)
Repayment of loan receivable	14	728	—
Net cash provided by/(used in) investing activities		**715**	**(20)**
Financing activities:			
Proceeds from issuing equity securities (Series A)	19	79,680	69,000
Proceeds from issuing equity securities (FLAC shareholders)	4	69,753	—
Proceeds from issuing equity securities (PIPE Financing)	4	228,343	—
Transaction costs on issue of shares	4	(2,534)	—
Proceeds from issuance of borrowings		—	—
Payments of lease liabilities	22	(65)	(10)
Net cash provided by financing activities		**375,177**	**68,990**
Net increase in cash		383,864	43,806
Foreign exchange differences		1,566	1,425
Cash at the beginning of the year		53,092	7,861
Cash at the end of the year	18	**438,522**	**53,092**

The accompanying notes are an integral part of these consolidated financial statements.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

Note 1 — Group Information

Corporate Information

NewAmsterdam Pharma Company N.V. (the "**Company**" and together with its subsidiaries, the "**Group**") is a global biotech company focused on the research and development of transformative therapies for cardio-metabolic diseases. The Company was incorporated in the Netherlands as a Dutch private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) under the name NewAmsterdam Pharma Company B.V. on June 10, 2022. On November 21, 2022, the Company's corporate form was converted to a Dutch public limited liability company (*naamloze vennootschap*) and its name was changed to NewAmsterdam Pharma Company N.V. The Group's principal place of business and registered office is Gooimeer 2-35, 1411 DC Naarden, The Netherlands. These consolidated financial statements comprise the financial statements of the Group. The Company is registered at the Chamber of Commerce under number 864035792.

In November 2022, the Group conducted an internal reorganization for the purpose of participating in the merger of the acquired company, Frazier Lifesciences Acquisition Corporation (**"FLAC"**) as described in Note 4. As a result of the internal restructuring and merger, NewAmsterdam Pharma, FLAC and NewAmsterdam Pharma Investment Corporation, a new Cayman-based exempted company, became wholly-owned subsidiaries of the Company.

The consolidated financial statements were authorized by the Company's Board of Directors (the "**Board**") for issuance on May 22, 2023.

Group Information

In November 2022, the Company became the ultimate parent company of the Group after an internal reorganization, as previously mentioned and as further described in Note 4.

As per December 31, 2022, the consolidated financial statements of the Group include:

Name	Legal seat	Country of incorporation	Percent equity interest 2022	Percent equity interest 2021
NewAmsterdam Pharma Holding B.V.	Naarden	The Netherlands	100%	100%
Frazier Lifesciences Acquisition Corporation ("FLAC")	United States of America	United States of America	100%	100%

NewAmsterdam Pharma Holding B.V. has two subsidiaries called NewAmsterdam Pharma B.V. and NewAmsterdam Pharma Corporation. FLAC is further described in Note 4.

Note 2 — Basis of Preparation and Summary of Significant Accounting Policies

Basis of Preparation

These consolidated financial statements have been prepared in accordance with International Financial Reporting Standards and the interpretations of the IFRS Interpretations Committee ("**IFRS IC**") as

issued by the International Accounting Standards Board ("IASB") and endorsed by the European Union and Title 9, Book 2 of the Dutch Civil code, effective at the time of preparing the consolidated financial statements of the Company. The consolidated financial statements have been prepared on a historical cost basis, unless otherwise disclosed.

The consolidated financial statements are presented in Euro ("**EUR**" or "**€**"). In these notes, Euro amounts are presented in thousands, except for share and per share amounts and as otherwise indicated.

Since NewAmsterdam Pharma Company N.V.'s statement of profit or loss for 2022 is recognized in the consolidated financial statements, it is sufficient in the Company's financial statements to present a condensed statement of profit or loss in accordance with section 402 of Book 2 of the Dutch Civil Code.

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 comprehensive loss, consolidated statements of financial position, consolidated statements of changes in equity and consolidated statements of cash flows 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 the Company.

All inter-company transactions and unrealized gains on transactions between the Company and its subsidiaries are eliminated.

Going Concern

The Group has incurred a net loss since its inception and for all periods presented. Management has assessed it appropriate to prepare these consolidated financial statements on a going concern basis, taking into account the cash balance of €438.5 million as at December 31, 2022. See Note 19 for more information regarding the capital structure of the Company. In June 2022, the Group entered into a licensing agreement with A. Menarini International Licensing S.A. ("**Menarini**"), whereby the Group received an upfront payment of €115.0 million in July 2022 in exchange for allowing Menarini to locally develop, obtain and maintain regulatory approval, and commercialize finished products containing obicetrapib and ezetimibe. See Note 5 for more information regarding the agreement with Menarini.

In November 2022, the Company completed the Business Combination (as defined below)

described in Note 4. The Company received proceeds of €69.8 million as a result of the Business Combination and €228.3 million as a result of the concurrent PIPE Financing. The proceeds from the Business Combination and the upfront payment from Menarini, along with the Company's cash, is expected to be sufficient to fund the Company's anticipated level of operations through 2026.

In this respect, management has not identified any material uncertainties that may cast a significant doubt about the Company's ability to continue to adopt the going concern basis of accounting for a period at least twelve months from the date when the consolidated financial statements are authorized for issue.

Consolidated Statement of Cash Flows

The Consolidated Statement of Cash Flows has been prepared using the indirect method. The cash disclosed in the Consolidated Statement of Cash Flows comprises of cash at bank.

Revenue

Under IFRS 15, to determine the recognition of revenue, the Company performs the following five steps:

1. identify the contract(s) with the customer;
2. identify the performance obligations in the in the contract;
3. determine the transaction price;
4. allocate the transaction price to the performance obligations in the contract; and
5. recognize revenue when (or as) the Company satisfies a performance obligation.

The Company performs an analysis to identify the performance obligations for its license agreement. Where a license agreement comprises several promises, it must be assessed whether these promises are capable of being distinct within the context of the contract. Promised goods or services are considered distinct when: (i) the customer can benefit from the good or service on its own or together with other readily available resources, and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, the Company considers factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on their own and whether the required expertise is readily available. In addition, the Company considers whether the customer can benefit from a promise for its intended purpose without the receipt of the remaining promises, whether the value of the promise is dependent on the unsatisfied promises, whether there are other vendors that could provide the remaining promises, and whether it is separately identifiable from the remaining promises.

The Company estimates the transaction price based on the amount of consideration the Company expects to receive for transferring the promised goods or services in the contract. The consideration may include both fixed consideration and variable consideration. At the inception of each arrangement that includes variable consideration, the Company evaluates the amount of the potential payments and the likelihood that the payments will be received. The Company utilizes either the most likely amount method or expected value method to estimate variable consideration to include in the transaction price based on which method better predicts the amount of consideration expected to be received. The amount

included in the transaction price is constrained to the amount for which it is highly probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment.

After the transaction price is determined, it is allocated to the identified performance obligations based on the estimated standalone selling price. The Company must develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. The Company utilizes key assumptions to determine the standalone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction, probabilities of technical and regulatory success and the estimated costs. Certain variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated to each performance obligation are consistent with the amounts the Company would expect to receive for each performance obligation.

Revenue is recognized when the customer obtains control of the goods and/or services as provided in the license agreement. 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. The Company recognizes revenue over time as the customer simultaneously receive the benefits provided by the Company's performance, satisfied over time.

Upfront licensing payments are recognized as revenue at the point in time when the Company transfers control of the license only if the license is determined to be a separate performance obligation from other undelivered performance obligations. Contingent development costs and milestone payments are generally included in the transaction price at the amount stipulated in the respective agreement and recognized to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur.

The Company will recognize royalty revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Research and Development Expense

Research and development costs are recognized as an expense when incurred and are typically made up of clinical and preclinical activities, drug development and manufacturing costs, and include costs for clinical research organizations and investigative sites. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as information provided by vendors on their actual costs incurred. The determination of the level of services performed by the vendors and the associated expenditure incurred for the services provided is made at each balance sheet date.

Development expenses are capitalized only if the cost involved can be measured reliably, the

product or process under development is technically feasible, future economic benefits are probable and the Group has the intention and resources to complete development and use or sell it. Due to the regulatory environment and other types of uncertainty, management has determined that the criteria for capitalizing development costs to intangible assets, as set out in IAS 38, have not been met and therefore the Group has not capitalized any development expenses in 2022, 2021 or 2020. Significant estimates and judgments are further described in Note 3.

Selling, General and Administrative Expenses

Expenses are recognized on the accrual basis when incurred by the Group.

Personnel Expenses

Wages and salaries, social security contributions, payroll taxes, bonuses, and other employee benefits are recognized on the accrual basis in which the employee provides the associated services.

The Group's pension plans are classified as defined contribution plans, and, accordingly, no pension obligations are recognized in the balance sheet. Costs relating to defined contribution plans are included in the income statement in the period in which they are incurred, and outstanding contributions are included in trade and other payables.

Share Listing Expense

The Merger with FLAC, as defined in Note 4, has been accounted for within the scope of IFRS 2, as FLAC does not constitute a business under IFRS 3. Based on IFRS 2 and from an analysis of the transaction, it has been considered that the excess of fair value of Ordinary Shares issued over the fair value of FLAC's identifiable net assets acquired represents compensation for the service of stock exchange listing for its shares and has been expensed as incurred.

Current Prepayments and Other Receivables

Prepayments are recognized upon the occurrence of a payment made for an expenditure during one accounting period that will be consumed and incurred in a future period. Prepayments expire and become expenses with the passage of time, use, or events. Value added tax receivable is measured at cost.

Expected credit losses

The Group applies the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for trade receivables. To measure the expected credit losses, trade receivables have been grouped based on shared credit risk characteristics and the days past due. Trade receivables are written off when there is no reasonable expectation of recovery. Indicators that there is no reasonable expectation of recovery include, amongst others, the failure of a debtor to engage in a repayment plan with the Group, and a failure to make contractual payments for a period of greater than 120 days past due. Impairment losses on trade receivables and contract assets are presented as net impairment losses within operating profit. Subsequent recoveries of amounts previously written off are credited against the same line item.

Income Taxes

Income tax expense represents the aggregate amount determined on the profit for the period based on current tax and deferred tax.

In cases where the tax relates to items that are charged to other comprehensive income or directly to equity, the tax is also charged respectively to other comprehensive income or directly to equity.

In evaluating the probability of recognizing income tax assets, management makes estimates related to the expectation of future taxable income, applicable tax opportunities, tax planning strategies, and recent financial performance. In making its assessment, management gives weight to positive and negative evidence that can be objectively verified. The carrying amount of deferred tax assets is reviewed at each reporting date 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.

Current tax

The tax currently payable is based on taxable profit for the year. Taxable profit differs from net profit as reported in profit or loss because it excludes items of income or expense that are taxable or deductible in other years and it further excludes items that are never taxable or deductible. The Group's liability for current tax is calculated using tax rates that have been enacted or substantively enacted by the end of the reporting period.

A provision is recognized for those matters for which the tax determination is uncertain but it is considered probable that there will be a future outflow of funds to a tax authority. The provisions are measured at the best estimate of the amount expected to become payable. The assessment is based on the judgment of tax professionals within the Group supported by previous experience in respect of such activities and in certain cases based on specialist independent tax advice.

Deferred taxation

Deferred tax is the tax expected to be payable or recoverable on differences between the carrying amounts of assets and liabilities in the financial statements and the corresponding tax bases used in the computation of taxable profit, and is accounted for using the liability method. Deferred tax liabilities are generally recognized for all taxable temporary differences and deferred tax assets are recognized to the extent that it is probable that taxable profits will be available against which deductible temporary differences can be utilized. Such assets and liabilities are not recognized if the temporary difference arises from the initial recognition (other than in a business combination) of other assets and liabilities in a transaction that affects neither the taxable profit nor the accounting profit. In addition, a deferred tax liability is not recognized if the temporary difference arises from the initial recognition of goodwill.

Deferred tax liabilities are recognized for taxable temporary differences arising on investments in subsidiaries and associates, and interests in joint ventures, except where the Group is able to control the reversal of the temporary difference and it is probable that the temporary difference will not reverse in the foreseeable future. Deferred tax assets arising from deductible temporary differences associated with such investments and interests are only recognized to the extent that it is probable that there will be sufficient taxable profits against which to utilize the benefits of the temporary differences and they are

expected to reverse in the foreseeable future.

The carrying amount of deferred tax assets is reviewed at each reporting date 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 is calculated at the tax rates that are expected to apply in the period when the liability is settled or the asset is realized based on tax laws and rates that have been enacted or substantively enacted at the reporting date.

The measurement of deferred tax liabilities and assets reflects the tax consequences that would follow from the manner in which the Group expects, at the end of the reporting period, to recover or settle the carrying amount of its assets and liabilities.

Deferred tax assets and liabilities are offset when there is a legally enforceable right to offset current tax assets against current tax liabilities and when they relate to income taxes levied by the same taxation authority and the Group intends to settle its current tax assets and liabilities on a net basis.

Current income tax is the expected tax expense, payable or receivable on taxable income or loss for the period, using tax rates enacted or substantively enacted at reporting date.

The Group has no income tax reported due to losses incurred in both periods presented.

Property, Plant and Equipment

Items of property, plant and equipment are initially recognized at cost. As well as the purchase price, cost includes directly attributable costs and the estimated present value of any future unavoidable costs of dismantling and removing items. The corresponding liability is recognized within provisions. They are subsequently measured at cost less accumulated depreciation and impairment losses.

Depreciation is provided on all items of property, plant and equipment so as to write off their carrying value over their expected useful economic lives or in the case of the right of use asset, over the shorter period of lease term and useful life of the underlying asset. Depreciation is provided at the following rates:

Computer equipment — 20% per annum straight line

The estimated useful life, 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.

Loan Receivable

Loan receivables are measured at amortized cost using the effective interest method, less any impairment losses, within the scope of IFRS 2. Interest receivable is included in financing income.

Intangible Assets

Intangible assets comprise of acquired in-process research and development (**"IPR&D"**) and was

initially recognized at cost, which was the consideration paid upon the asset acquisition of NewAmsterdam Pharma B.V. in 2020. In connection with the asset acquisition, contingent consideration for future profit rights and IPO share right was initially recognized as contingent consideration and had not been included in the carrying amount of the asset at acquisition. Management deemed that the events considered in estimating the contingent consideration were uncertain and could not be reliably estimated. For these reasons, the Company accounted for the contingent consideration under the cost accumulation model and not initially recognize a liability.

In accordance with IFRS 2, the additional contingent consideration paid for the IPR&D asset in exchange for shares in the Company upon the Closing Date (as defined below) is a share-based payment that is to be recognized at its fair value upon the date of the exchange. 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. Refer to Note 4 and Note 15 for additional details behind the acquisition and related cost recognized as IPR&D. The acquired IPR&D asset is regarded as having an indefinite useful life while in-progress as there is no foreseeable limit to the period over which the asset is expected to generate future cash flows, and the useful life will be determined once finalized.

Impairment of Intangible Assets

At each reporting date, the Group reviews the carrying amounts of its intangible assets with a definite life 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 to determine the extent of the impairment loss (if any). Where the asset does not generate cash flows that are independent from other assets, the Group estimates the recoverable amount of the cash-generating unit to which the asset belongs. A cash generating unit is the smallest identifiable group of assets that generates cash inflows that are largely independent of the cash inflows from other assets or groups of assets. When a reasonable and consistent basis of allocation can be identified, corporate assets are also allocated to individual cash-generating units, or otherwise they are allocated to the smallest group of cash-generating units for which a reasonable and consistent allocation basis can be identified.

Intangible assets with an indefinite useful life are tested for impairment at least annually and whenever there is an indication at the end of a reporting period that the asset may be impaired.

Recoverable amount is the higher of fair value less costs of disposal and value in use. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset for which the estimates of future cash flows have not been adjusted. The value in use amount is sensitive to the discount rate used in our discounted cash flow model as well as the expected future cash-inflows and the growth rate used for extrapolation purposes. Future cash flows are dependent on internal budgets and forecasts, whereas the discount rate depends on the interest rate and risk premium associated with the asset. Assumptions and estimates about future values of intangible assets are complex and subjective. They can be affected by a variety of factors, including external factors such as industry and economic trends, and internal factors such as changes in business strategy and internal forecasts.

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 profit or loss.

At the end of each reporting period, the Group determines if there is any indication a previously impaired intangible asset, excluding goodwill, no longer exists, has had a change in the estimates used to determine the asset's recoverable amount since the impairment loss was recognized. If indicators are identified, the Group determines if the recoverable amount is greater than its carrying amount. If the recoverable amount is greater than its carrying amount, impairment is reversed. Where an impairment loss subsequently reverses, the carrying amount of the asset (or cash-generating unit) 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 to the extent that it eliminates the impairment loss which has been recognized for the asset in prior years.

Financial Liabilities

Financial liabilities within the scope of IFRS 9 are classified as financial liabilities at fair value through profit or loss ("**FVTPL**") or at amortized cost, as appropriate. The Group determines the classification of its financial liabilities at initial recognition. A financial liability is classified as at FVTPL if it is classified as held-for-trading, it is a derivative, or it is designated as such on initial recognition. Financial liabilities at FVTPL are measured at fair value and net gains and losses, including any financing expense, are recognized in profit or loss. Financing expense and foreign exchange gains and losses are recognized in profit or loss. Any gain or loss on derecognition is also recognized in profit or loss.

The Group's financial liabilities include trade and other financial payables, derivative warrant liabilities and derivative earnout liability.

The net identifiable assets acquired in connection with the merger with FLAC included warrants that were issued in connection with FLAC's Initial Public Offering (the "**Public Warrants**") and the warrants issued by FLAC in a private offering which closed concurrently with its Initial Public Offering (the "**Private Placement Warrants**") which are further described at Note 4. Those instruments fall within the scope of IAS 32 and have been classified as a derivative financial liability.

The derivative warrant liabilities and derivative earnout liability are accounted for as financial instruments measured at fair value through profit or loss, as their characteristics meet the definition of a derivative, as noted in Note 17. In accordance with IFRS 9, such derivative financial instruments were initially recognized at fair value and subsequently remeasured at fair value through profit or loss.

The Group derecognizes a financial liability when its contractual obligations are discharged or cancelled or expire. The Group also derecognizes a financial liability when its terms are modified and the cash flows of the modified liability are substantially different, in which case a new financial liability based on the modified terms is recognized at fair value. On derecognition of a financial liability, the difference between the carrying amount extinguished and the consideration paid (including any non-cash assets transferred or liabilities assumed) is recognized in profit or loss. The cash flows regarding

financial liabilities are presented as gross in the consolidated statement of cash flows regardless of their maturity date.

Cash

Cash comprise cash and short-term bank deposits with an original maturity of three months or less. The carrying amount of these assets is approximately equal to their fair value due to their short term nature. Cash at the end of the reporting period as shown in the consolidated statement of cash flows can be reconciled to the related items in the consolidated reporting position as shown below.

Equity and reserves

No gain or loss is recognized in profit or loss on the purchase, sale, issue or cancellation of the Company's own equity instruments. Any difference between the carrying amount and the consideration, if reissued, is recognized in share premium.

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.

Share-based Payments

The Company operates equity-settled share-based payment arrangements, under which the Company and its subsidiaries receive services from directors, employees and others providing similar services as consideration for equity instruments of the Company.

The Company determines the fair value of the share-based payment awards at the grant date, including the impact of any market conditions and non-vesting conditions, and recognizes an expense for the services received over the service period, with a corresponding increase in equity. For awards with graded-vesting features, each installment of the award is treated as a separate grant, which means that each installment is separately expensed over the related vesting period. At the end of each reporting period, service conditions and non-market vesting conditions are taken into account when estimating the number of awards that will ultimately vest.

The total amount to be expensed for services received is determined by reference to the grant date fair value of the awards. For options, the grant date fair value is determined using an option valuation model. For restricted stock units, the grant date fair value is equal to the closing share price at the grant date.

Determining the fair value of share-based payment transactions requires the most appropriate valuation for the specific program, which depends on the underlying terms and conditions. This estimate also requires the determination of the most appropriate inputs to the valuation model, including the fair value of the share option. Management determines the value of share-based awards at the respective grant date and at the end of each reporting period with the assistance of a third-party valuation specialist using certain assumptions, such as share price volatility, the determination of an appropriate risk-free interest rate and expected dividends. For options granted under the Company's long-term incentive plan, the total amount to be expensed for services received is determined by reference to the grant date fair

value of the options granted as determined using the Black-Scholes pricing model. The Black-Scholes model requires management to make assumptions and judgments about the variables used in the calculations, including the expected term (weighted-average period of time that the options granted are expected to be outstanding), the expected volatility of Ordinary Shares, the related risk-free interest rate and the expected dividend. Changes in these estimates can have a material effect on share-based expenses recognized.

If the terms and conditions on which an award was granted are modified, the Company recognizes the effects of the modification if it increases the total fair value of the share-based payment arrangement or is otherwise beneficial to the participant. If an award is cancelled or settled during the vesting period and a new award is granted as a replacement award, the Company accounts for the grant of the replacement award as a modification. The incremental fair value is the difference between the fair value of the replacement award and the net fair value of the cancelled award at the date the replacement award is granted. If an incremental fair value is granted, it is recognized over the remaining vesting period in addition to the expense recognized for the original award.

Employer social security contributions payable in connection with share-based payment awards are accounted for as cash-settled share-based payment transactions. The expense for such employer social security contributions is allocated over the vesting period based on the estimated fair value of the liability. From the end of the vesting period to the date of actual exercise of options, the fair value of the liability is remeasured, with any changes in fair value recognized in profit or loss.

Leases

Right of use asset

Leased assets are capitalized at the commencement date of the lease and comprise the initial amount, initial direct costs incurred when entering into the lease less any lease incentives. An impairment is undertaken for any right of use lease assets that shows indicators of impairment and an impairment less is recognized against any right of use lease assets that is impaired. Right of use assets are amortized straight-line over the shorter period of lease term and useful life of the underlying asset. See Note 22 for details of the leasing arrangement.

Lease liability

The lease liability is measured at the present value of the fixed and variable lease payments net of cash lease incentives that are not paid at the balance date. Lease payments are apportioned between the finance charges and reduction of the lease liability using the incremental borrowing rate implicit in the lease to achieve a constant rate of interest on the remaining balance of the liability. Lease payments for buildings exclude services fees for cleaning and other costs. Lease modifications are accounted for as a new lease with an effective date of the modification.

Fair value measurement

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value of a liability reflects its non-performance risk.

The Group measures the fair value of an instrument using the quoted price in an active market for that instrument, if that price is available. A market is regarded as 'active' if transactions for the asset or liability take place with sufficient frequency and volume to provide pricing information on an ongoing basis.

If there is no quoted price in an active market, then the Group uses valuation techniques that maximize the use of relevant observable inputs and minimize the use of unobservable inputs. The chosen valuation technique incorporates all the factors that market participants would take into account in pricing a transaction.

The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest. The Group uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximizing the use of relevant observable inputs and minimizing the use of unobservable inputs. All assets and liabilities for which fair value is measured or disclosed in the consolidated financial statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1: Quoted (unadjusted) market prices in active markets for identical assets or liabilities.
- Level 2: Inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly (i.e. as prices) or indirectly (i.e. derived from prices).
- Level 3: Inputs for the asset or liability that are not based on observable market data (unobservable inputs).

If the inputs used to measure the fair value of an asset or a liability fall into different levels of the fair value hierarchy, then the fair value measurement is categorized in its entirety in the same level of the fair value hierarchy as the lowest level input that is significant to the entire measurement.

For assets and liabilities that are recognized in the consolidated financial statements at fair value on a recurring basis, the Group determines whether transfers have occurred between levels in the hierarchy by re-assessing categorization (based on the lowest level input that is significant to the fair value measurement as a whole), at the end of each reporting period.

New and Amended IFRS Standards that are Effective for the Current Year

New standards and interpretations effective for the annual period beginning on January 1, 2022 did not have any material impact on the Company's consolidated financial statements.

Annual Improvements to IFRS Standards 2018-2020 — Amendments to IFRS 1 — First-Time Adoption of International Financial Reporting Standards (Effective January 1, 2022)

The amendment permits a subsidiary that applies paragraph D16(a) of IFRS 1 to measure cumulative translation differences using the amounts reported by its parent, based on the parent's date of transition to IFRSs.

Annual Improvements to IFRS Standards 2018-2020 — Amendments to IFRS 9 — Financial Instruments (Effective January 1, 2022)

The amendment clarifies fees in the applying the '10 percent' test for derecognition of financial

liabilities.

Annual Improvements to IFRS Standards 2018-2020 — Amendments to IAS 41 — Agriculture (Effective January 1, 2022)

The amendment removes the requirement in paragraph 22 of IAS 41 for entities to exclude taxation cash flows when measuring the fair value of a biological asset using a present value technique removes the requirement in paragraph 22 of IAS 41 for entities to exclude taxation cash flows when measuring the fair value of a biological asset using a present value technique.removes the requirement in paragraph 22 of IAS 41 for entities to exclude taxation cash flows when measuring the fair value of a biological asset using a present value technique.

Amendments to IFRS 3 — Reference to the Conceptual Framework (Effective January 1, 2022)

The amendments add to IFRS 3 a requirement that, for obligations within the scope of IAS 37, an acquirer applies IAS 37 to determine whether at the acquisition date a present obligation exists as a result of past events. For a levy that would be within the scope of IFRIC 21 Levies, the acquirer applies IFRIC 21 to determine whether the obligating event that gives rise to a liability to pay the levy has occurred by the acquisition date. Finally, the amendments add an explicit statement that an acquirer does not recognize contingent assets acquired in a business combination.

Amendments to IAS 16 — Property, Plant and Equipment — Proceeds before Intended Use (Effective January 1, 2022)

The amendments prohibit deducting from the cost of an item of property, plant and equipment any proceeds from selling items produced before that asset is available for use. Consequently, an entity recognizes such sales proceeds and related costs in profit or loss and measures the cost of those items in accordance with IAS 2 Inventories.

The amendments also clarify the meaning of ‘testing whether an asset is functioning properly’. IAS 16 now specifies this as assessing whether the technical and physical performance of the asset is such that it is capable of being used in the production or supply of goods or services, for rental to others, or for administrative purposes. If not presented separately in the statement of comprehensive income, the financial statements shall disclose the amounts of proceeds and cost included in profit or loss that relate to items produced that are not an output of the entity’s ordinary activities, and which line item(s) in the statement of comprehensive income include(s) such proceeds and cost.

Amendments to IAS 37 — Onerous Contracts — Cost of Fulfilling a Contract (Effective January 1, 2022)

The amendments specify that the ‘cost of fulfilling’ a contract comprises the ‘costs that relate directly to the contract’. Costs that relate directly to a contract consist of both the incremental costs of fulfilling that contract (examples would be direct labor or materials) and an allocation of other costs that relate directly to fulfilling contracts (an example would be the allocation of the depreciation charge for an item of property, plant and equipment used in fulfilling the contract). The amendments apply to contracts for which the entity has not yet fulfilled all its obligations at the beginning of the annual reporting period in which the entity first applies the amendments. Comparatives are not restated. Instead, the entity shall recognize the cumulative effect of initially applying the amendments as an adjustment to the opening balance of retained earnings or other component of equity, as appropriate, at the date of initial application.

New Standards, Interpretations and Amendments Issued but Not Yet Adopted by the Company

At the date of authorization of these financial statements, the Company has not applied the following new and revised IFRS Standards that have been issued but are not yet effective. The amendments to the standards and interpretations presented are not expected to have a material impact on the consolidated financial statements in future periods. Any new or amended standards and interpretations that are not deemed relevant to the Group's consolidated financial position and results of operations are not listed.

Amendments to IAS 1 — Presentation of Financial Statements — Classification of liabilities as Current and Non-current (Effective January 1, 2023)

The amendments to IAS 1 affect only the presentation of liabilities as current or non-current in the statement of financial position and not the amount or timing of recognition of any asset, liability, income or expense, or the information disclosed about those items.

The amendments clarify that the classification of liabilities as current or non-current is based on rights that are in existence at the end of the reporting period, specify that classification is unaffected by expectations about whether an entity will exercise its right to defer settlement of a liability, explain that rights are in existence if covenants are complied with at the end of the reporting period, and introduce a definition of 'settlement' to make clear that settlement refers to the transfer to the counterparty of cash, equity instruments, other assets or services.

Amendments to IAS 1 — Presentation of Financial Statements and IFRS Practice Statement 2 — Making Materiality Judgments — Disclosure of Accounting Policies (Effective January 1, 2023)

The amendments change the requirements in IAS 1 with regard to disclosure of accounting policies. The amendments replace all instances of the term 'significant accounting policies' with 'material accounting policy information'. Accounting policy information is material if, when considered together with other information included in an entity's financial statements, it can reasonably be expected to influence decisions that the primary users of general purpose financial statements make on the basis of those financial statements.

The supporting paragraphs in IAS 1 are also amended to clarify that accounting policy information that relates to immaterial transactions, other events or conditions is immaterial and need not be disclosed. Accounting policy information may be material because of the nature of the related transactions, other events or conditions, even if the amounts are immaterial. However, not all accounting policy information relating to material transactions, other events or conditions is itself material.

The Board has also developed guidance and examples to explain and demonstrate the application of the 'four-step materiality process' described in IFRS Practice Statement 2.

Amendments to IAS 8 — Accounting Policies, Changes in Accounting Estimates and Errors — Definition of Accounting Estimates (Effective January 1, 2023)

The amendments replace the definition of a change in accounting estimates with a definition of accounting estimates. Under the new definition, accounting estimates are "monetary amounts in financial statements that are subject to measurement uncertainty."

The definition of a change in accounting estimates was deleted. However, the Board retained the

concept of changes in accounting estimates in the Standard with the following clarifications:

- A change in accounting estimate that results from new information or new developments is not the correction of an error.
- The effects of a change in an input or a measurement technique used to develop an accounting estimate are changes in accounting estimates if they do not result from the correction of prior period errors.

Amendments to IAS 12 — Income Taxes — Deferred Tax related to Assets and Liabilities arising from a Single Transaction (Effective January 1, 2023)

The amendments introduce a further exception from the initial recognition exemption. Under the amendments, an entity does not apply the initial recognition exemption for transactions that give rise to equal taxable and deductible temporary differences.

Depending on the applicable tax law, equal taxable and deductible temporary differences may arise on initial recognition of an asset and liability in a transaction that is not a business combination and affects neither accounting nor taxable profit. For example, this may arise upon recognition of a lease liability and the corresponding right-of-use asset applying IFRS 16 at the commencement date of a lease.

Following the amendments to IAS 12, an entity is required to recognize the related deferred tax asset and liability, with the recognition of any deferred tax asset being subject to the recoverability criteria in IAS 12.

The amendments apply to transactions that occur on or after the beginning of the earliest comparative period presented. In addition, at the beginning of the earliest comparative period an entity recognizes:

- A deferred tax asset (to the extent that it is probable that taxable profit will be available against which the deductible temporary difference can be utilized) and a deferred tax liability for all deductible and taxable temporary differences associated with:
  - Right-of-use assets and lease liabilities; or
  - Decommissioning, restoration and similar liabilities and the corresponding amounts recognized as part of the cost of the related asset.
- The cumulative effect of initially applying the amendments as an adjustment to the opening balance of retained earnings (or other component of equity, as appropriate) at that date.

The impact on the Company of the related amendment is still under evaluation.

Amendments to IAS 1 — Presentation of Financial Statements — Classification of Liabilities as Current or Non-current (Effective January 1, 2024)

Published in 2020, the amendments clarify that the classification of liabilities as current or noncurrent is based solely on a company's right to defer settlement for at least 12 months at the reporting date. The right needs to exist at the reporting date and must have substance.

The amendments also clarify that the transfer of a company's own equity instruments is regarded as settlement of a liability. If a liability has any conversion options, then those generally affect its classification as current or noncurrent, unless these conversion options are recognized as equity under IAS 32, Financial Instruments: Presentation.

The impact on the Company of the related amendment is still under evaluation.

Note 3 — Use of 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.

Revenue

Critical Judgment

The Group performs an analysis to identify the performance obligations for its license agreement. Under IFRS 15, the Group applies significant judgment when evaluating (i) whether the obligations under these agreements represent one or more combined performance obligations, (ii) the determination of whether the reimbursable development costs and milestone payments should be included in the transaction price, (iii) the allocation of the transaction price between the identified performance obligations and (iv) the timing of satisfaction of the identified performance obligations. As further detailed at Note 5, management concluded that two performance obligations exist under the Menarini License: a license performance obligation, which comprises of interrelated licenses granted under the agreement, and a research and development performance obligation which corresponds to the reimbursement of certain research and development expenditures.

Critical Estimate

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 costs that are completed each period compared to the total estimated costs. A cost-based input method of revenue recognition requires management to make estimates of costs to complete the Company's performance obligation. In making such estimates, significant judgment is required to evaluate assumptions related to cost estimates. The cumulative effect of revisions to estimated costs to complete the Company's performance obligation will be recorded in the period in which changes are identified and amounts can be reasonably estimated. A significant change in these assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods.

The Group allocated the initial transaction price of the Menarini License across both performance obligations based upon a relative stand-alone selling price basis by applying an expected cost plus margin approach. As a result, a portion of the initial transaction price has been deferred from recognition until the expected timing of the associated research and development services have been attained. Such costs and timing are dependent upon forecasted research and development costs which generally follow the remaining term of contracted studies. Significant management judgment is driven by critical estimates such as the forecasted cost and timing of clinical studies, as further described below, which

are required to determine the level of effort and the expected period to complete the performance obligations under the Menarini License. Significant changes in the forecasted research and development costs, including when such costs are incurred, can have a material effect on the timing and amount of revenue recognized.

Research and Development Expense

Research and development expenses are currently not capitalized but are expensed because the criteria for capitalization are not met (see Note 2 and Note 6). At each balance sheet date, the Group estimates the level of services performed by the vendors and the associated expenditure incurred for the services performed.

Quantification of the research and development expenses incurred during the period requires judgment based on key estimates comprising of non-financial data, because the progress of activities is not directly observable and therefore the precise timing of the R&D activities may not be entirely certain. In estimating progress toward completion of specific tasks, the Group therefore uses non-financial data such as number of patient screenings, patient visits, patient enrollment, clinical site activations and vendor information of actual costs incurred. This data is obtained through reports from outside service providers as to the progress or state of completion of trials or the completion of services and reviewed by Group personnel. Management's judgments based on this non-financial data have not changed during the financial periods presented. Due to the nature of the expense it is not practicable to give meaningful sensitivity estimates due to the large volume of variables that contribute to the research and development expenses.

Financial Derivative Liabilities

According to management’s assessment, the Public Warrants, Private Placement Warrants and Earnout Shares for Participating Shareholders fall within the scope of IAS 32 and have been classified as derivative financial liabilities. In accordance with IFRS 9 guidance, derivatives that are classified as financial liabilities shall be measured at fair value with subsequent changes in fair value to be recognized in profit and loss.

On the Closing Date, the initial fair value of the Public Warrants was based on the actively quoted market price, and the initial fair value of the Private Placement Warrants was derived from the quoted price of the Public Warrants given the terms being nearly identical. For further details regarding the inputs and assumptions inherent in the warrants’ valuation, refer to Note 17.

The Earnout Shares for Participating Shareholders are recognized as a financial derivative earnout liability carried at FVTPL by reference to Level 3 measurement inputs because a quoted or observable price for the instrument or an identical instrument is not available in active markets. The fair value of the earnout is determined using a Black-Scholes pricing model using inputs as outlined at Note 17. The expected probability of milestone completion triggering issuance of the Earnout Shares represents the most significant unobservable input utilized in this Level 3 valuation technique in driving the fair value measurement. The calculated fair value would increase (decrease) if the probability was higher (lower). For further details regarding the inputs and assumptions inherent in the Earnout Shares’ valuation model, refer to Note 17.

Note 4 — FLAC Merger and Capital Reorganization

Prior to November 22, 2022, NewAmsterdam Pharma Company N.V. was a shell company with

no active trade or business, and all relevant assets and liabilities, as well as income and expenses, were borne by NewAmsterdam Pharma Holding B.V. ("**NewAmsterdam Pharma**"). FLAC was a special purpose acquisition company ("**SPAC**") incorporated on October 7, 2020 as a Cayman Islands exempted company formed for the purpose of effecting a merger, share exchange, asset acquisition, share purchase, reorganization or a similar business combination. FLAC completed its initial public offering on December 11, 2020 and listed on the Nasdaq.

On July 25, 2022, FLAC entered into a Business Combination Agreement ("**Business Combination Agreement**") with NewAmsterdam Pharma, the Company, and NewAmsterdam Pharma Investment Corporation, a Cayman Islands exempted company and wholly owned subsidiary of the Company.

On the Closing Date, pursuant to the terms of the Business Combination Agreement, the following transactions occurred (collectively, the "**Business Combination**").

- On the date prior to the Closing Date, the shareholders of NewAmsterdam Pharma ("**Participating Shareholders**") exchanged their interest for ordinary shares in the share capital of the Company ("**Ordinary Shares**") such that the Company became the direct parent of NewAmsterdam Pharma (the "**Exchange**"). The Exchange is accounted for as a capital reorganization, with NewAmsterdam Pharma being the accounting predecessor. In connection with the Exchange, 17,016,872 NewAmsterdam Pharma shares of €0.01 par value were exchanged at a ratio of approximately 2.13 for 36,258,312 Ordinary Shares, €0.12 par value per share which resulted in a €4.2 million increase in share capital and an offsetting decrease in share premium (See Note 19).
- Immediately after giving effect to the Exchange, a subsidiary of the Company merged with and into FLAC (the "**Merger**"), with FLAC surviving as a wholly owned subsidiary of the Company. The merger of FLAC constituted a transaction by the Company which is accounted for within the scope of IFRS 2, as the acquired company of FLAC does not meet the definition of a business pursuant to IFRS 3, Business Combinations.

In exchange, the Company received the following identifiable net assets held by FLAC on the Closing Date:

	2022
Fair value of shares issued to FLAC shareholders	**126,667**
Less FLAC identifiable net assets:	
Cash held in FLAC's trust account	69,779
Derivative warrant liabilities assumed	(3,712)
Total FLAC identifiable net assets	**66,067**
Share listing expense - share-based compensation for listing cost	**60,600**

In accordance with IFRS 2, the difference between the fair value of the net assets contributed by FLAC and the fair value of equity instruments provided to former FLAC shareholders is treated as an expense, resulting in a €60.6 million share listing expense classified within the loss for the year (See Note 9) and an increase in equity representing the fair value of the shares issued at a price of $9.87.

- Immediately following the Merger, each outstanding warrant to purchase a Class A ordinary share, par value $0.0001 per share, of FLAC became a warrant to purchase one Ordinary Share, on the same contractual terms which resulted in the issuance of 167,000 Private Placement Warrants and 4,600,000 Public Warrants (collectively, the "**Warrants**").

- Each NewAmsterdam Pharma option that was outstanding and unexercised remained outstanding, and to the extent unvested, such option will continue to vest in accordance with its applicable terms, and at the time of the Exchange, such NewAmsterdam Pharma options became options to purchase, and will when exercised be settled in Ordinary Shares.
- In addition to the transactions described above, 8,656,330 Ordinary Shares were issued to Saga Investments Coöperatief U.A. ("**Amgen**") and Mitsubishi Tanabe Pharma Corporation ("**MTPC**") pursuant to their profit rights granted upon the acquisition of Dezima Pharma B.V. (See Note 15).
- Following the Merger, upon the achievement of a certain clinical development milestone, the Company will issue to the Participating Shareholders, Amgen, MTPC and holders of options to purchase shares of NewAmsterdam Pharma prior to the closing of the Business Combination, who were directors, officers, employees or consultants of NewAmsterdam Pharma as of the date of the Business Combination Agreement and who are at the time of achievement of such milestone still providing services to the Group (the "**Participating Optionholders**"), 1,886,137 additional Ordinary Shares (the "**Earnout Shares**"), which in the case of the Participating Optionholders will take the form of awards of restricted stock units. As a result, 1,725,358 Earnout Shares are currently allocated to the Participating Shareholder, including Amgen and MTPC which is discussed in Note 17. Additionally, 160,778 Earnout Shares are currently allocated to Participating Optionholders discussed in Note 17.
- The Company raised an additional €228.3 million in net equity proceeds through a private placement of ordinary shares with existing shareholders of NewAmsterdam Pharma, FLAC and other new investors (the "**PIPE Financing**"). The PIPE Financing was treated as a capital contribution, which resulted in increases of €2.8 million and €225.5 million to share capital and share premium, respectively.

Both the Merger and PIPE Financing closed as of November 22, 2022. Upon consummation of the transactions, the Company's Ordinary Shares began trading on the Nasdaq under the ticker NAMS. The Public Warrants are traded under the ticker NAMSW. The Company incurred incremental transaction costs directly attributable to the issuance of new shares to FLAC shareholders and the PIPE Financing of €2.5 million, which is netted against the equity proceeds as a reduction in share premium.

The Company also amended existing share-based compensation agreements held by employees of NewAmsterdam Pharma Holding prior to the Merger (see Note 20), in addition to making additional share-based payments to key management personnel (see Note 23).

Note 5 — Revenue

Revenue consisted of the following for the years ended December 31:

	2022	2021
License revenue attributed from license performance obligation	93,500	—
License revenue attributed from R&D performance obligation	4,000	—
Total revenue	**97,500**	**—**

On June 23, 2022, NewAmsterdam Pharma entered into a licensing agreement with A. Menarini International Licensing S.A. ("**Menarini**") (the "**Menarini License**"), pursuant to which it granted Menarini an exclusive, royalty-bearing, sublicensable license under certain of its intellectual property

and its regulatory documentation to undertake post approval development activities and commercialize multiple brands of obicetrapib, either as a sole active ingredient product or in a fixed dose combination with ezetimibe (the "**Licensed Products**"), for any use in the majority of European Countries ("**Menarini Territory**").

The Group remains responsible for the development and commercialization costs related to Licensed Products, excluding local development, regulatory and commercialization costs incurred by Menarini in the Menarini Territory. In addition, Menarini is expected to purchase the Licensed Products from the Group in accordance with a supply agreement that is to be executed following the execution of the Menarini License and prior to commercialization. As such, the Company determined that the agreements should not be combined as a single contract pursuant to the guidance prescribed in IFRS 15.

The Menarini License includes a non-refundable upfront payment, fixed reimbursements for the Group's continued development costs, payments based upon the achievement of defined development, regulatory and commercial milestones, sales-based royalties, and certain cost sharing payments made by Menarini to the Group and by the Group to Menarini.

The Company has evaluated the Menarini License based on the requirements of IFRS 15 Revenue Recognition and has concluded the following:

Within the license performance obligation described below, there are various licenses granted under the Menarini License which currently in place do not represent distinct performance obligations in themselves, as the licenses are highly interrelated and Menarini would likely be unable to derive significant benefits from their access to these licenses on an individual basis.

The Company, considering that (i) there are no material restrictions included in the contract which would prevent Menarini to direct the use of, and obtain substantially all of the remaining benefits and (ii) the majority of the Company's remaining development activities are in late-stage development and are not expected to significantly affect the functionality of the underlying intellectual property, 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 licenses to Menarini is to provide a right to use the Group's intellectual property as it exists at the point in time at which the license is granted and therefore, revenue accrued and allocated to this performance obligation has been recognized at a point in time.

The Company has also identified an additional performance obligation that consists of the research and development activities related to the general development and commercialization costs related to Licensed Products. The Company determined that this performance obligation is satisfied over time as Menarini simultaneously receives and consumes the benefits of the services provided as they are performed. This is based on the fact that Menarini is receiving status of the research periodically which allows it to make informed decisions in its local development activities. The Company further considered that the licenses and the R&D services are not highly interdependent or highly interrelated because the Group is able to fulfill its promise to transfer the licenses regardless of fulfilling its promise to perform the remaining R&D services. The Company also concluded that the licenses are considered distinct as Menarini could benefit from the licenses together with readily available resources other than the Company's research and development services. The Company utilizes a cost-based input method to measure its progress toward completion of its performance obligation and to calculate the corresponding

amount of revenue to recognize each period. The Company believes this is the best measure of progress because other measures do not reflect how the Company transfers its performance obligation to Menarini. In applying the cost-based input method of revenue recognition, the Company uses actual clinical study enrollment figures as well as actual costs incurred relative to budgeted costs expected to be incurred attributable to the Menarini Territory for the performance obligation. These costs consist primarily of third-party contract costs relative to the level of patient enrollment in the studies. Revenue will be recognized based on the level of costs incurred relative to the total budgeted costs for the performance obligation.

As such, two performance obligations for the Menarini License were identified at contract inception, comprising a license to use the Company's IP (the "license performance obligation") and a promise to continue the development activities for the licensed compound (the "R&D performance obligation").

The Company's assessment of the transaction price included an analysis of amounts it expected to receive, which at contract inception consisted of the non-refundable, upfront payment of €115.0 million that was received by the Group in July 2022. The Company considers this non-refundable fee of €115.0 million to be the initial transaction price.

The Company has allocated the transaction price to each performance obligation identified on a relative stand-alone selling price basis. The Company has used a combination of methods to calculate the stand-alone selling prices, using the expected cost plus a margin approach to calculate the standalone selling price of the research and development services required in the Menarini License and needed to commercialize obicetrapib in the Menarini Territory and the residual approach to calculate the stand-alone selling price for the license based on the fair value of the total promised goods and services in the Menarini License considering that the Company has not yet established a price for licenses, has not historically sold licenses on a stand-alone basis (i.e., the selling price is uncertain), and the amount allocated is consistent with the allocation objective as the Company believes the stated upfront amount is consistent with a risk-adjusted price that a market participant would be willing to pay for the licenses.

At contract inception, the Company has allocated €93.5 million to the license performance obligation, recognized as "revenue" in the condensed consolidated statement of profit and €21.5 million to the R&D performance obligation, recognized as "deferred revenue" in the condensed consolidated statement of financial position. In the fourth quarter of 2022, additional costs were added to the studies required to satisfy the R&D performance obligation, which resulted in a cumulative-effect adjustment to the denominator used in the cost-based input method that was greater than the costs identified upon inception of the Menarini License term. As a result, for the year ended December 31, 2022, the Company recognized revenue of €4.0 million in connection with R&D services performed under the Menarini License. There may be additional costs added to the studies required to satisfy the R&D performance obligation in the future. Assuming a 50% increase in total estimated costs as of December 31, 2022, revenue recognition related to the R&D performance obligation for the year ended December 31, 2022 would have decreased by approximately €1.2 million.

The deferred revenue has been recognized within current and non-current liabilities based on the expected timing of the associated research and development services. In connection with the Menarini License, €13.0 million has been recognized as current liabilities as the Company expects to perform the

associated services within twelve months after the reporting period and the remaining €4.5 million has been recognized as non-current liabilities as of December 31, 2022.

The following table presents changes in the balance of the Company's deferred revenue (in thousands):

	2022	2021
Beginning balance on January 1	—	—
Addition of deferred revenue under the Menarini License	21,500	—
Revenue recognized under the Menarini License during the period	(4,000)	—
Ending balance on December 31	**17,500**	**—**

The Company allocated the upfront payment of €115 million to the identified performance obligations based on the combined license performance obligation and recognized the upfront payment as revenue at a point in time upon satisfaction of the performance obligation, which was achieved at the execution of the Menarini License.

Additionally, in partial contribution to the Company's costs of development of the Licensed Products, Menarini will pay the Group €27.5 million, payable in two equal annual installments, together with bearing 50% of any development costs incurred in respect of the pediatric population in the Menarini Territory. Due to the scientific uncertainties around the commercialization of the Licensed Products based on the success of clinical trials, out of the control of the Company, the fixed €27.5 million is considered constrained at contract execution and is not initially recognized within the transaction price until it becomes highly probable of no significant revenue reversal. If certain conditions are not met, then the Group does not have the right to payment. At the end of each reporting period, the Company will assess the probability of significant reversals for any amounts that become likely to be realized prior to recognizing the fixed consideration associated with these payments within the transaction price. To date, the Group has not received any reimbursement payments.

The Menarini License also provides for certain milestone payments from Menarini to the Group upon the achievement of specified development, regulatory and commercial milestones linked to the enhanced value of the license performance obligation. More specifically, the Group is eligible to receive up to an additional €863 million upon the achievement of various clinical, regulatory and commercial milestones. These milestones are contingent payments. These milestone payments represent variable consideration that are not initially recognized within the transaction price, due to the scientific uncertainties around the commercialization of the Licensed Products based on the success of clinical trials. At the end of each reporting period, the Company will assess the probability of significant reversals for any amounts that become likely to be realized prior to recognizing the variable consideration associated with these payments within the transaction price. To date, the Company has not received any milestones payments.

Lastly, the Group is entitled to receive tiered royalty payments based on annual aggregate net sales of all Licensed Products in the Menarini Territory, subject to specified reductions upon commercialization. The royalty term begins for each Licensed Product on a country-by-country basis upon the first commercial sale of such product in such country and ends on the later of (i) the expiration of the last-to-expire patent that includes a valid claim, (ii) the expiration of regulatory exclusivity in such country for such Licensed Product and (iii) a specified number of years after the first commercial

sale of such Licensed Product in such country (the term of the agreement). In accordance with IFRS 15, the Company recognizes revenue from royalty payments at the later of (i) the occurrence of the subsequent sale; or (ii) the performance obligation to which some or all of the sales-based milestone or royalty payments has been allocated has been satisfied. The Company anticipates recognizing these royalty payments if and when subsequent sales are generated from the Licensed Products.

The Group has incurred €3.1 million of costs to obtain the Menarini License related to unavoidable costs from the Company's financial advisor assisting in the negotiation. These costs have been proportionally allocated to the identified performance obligations on a relative standalone selling price basis as previously discussed. Based on that, €2.5 million has been recognized as "selling, general and administrative expenses" related to the satisfied license performance obligation, €0.5 million has been capitalized as "prepayments and other receivables," and €0.1 million has been capitalized as "long term prepaid expenses," of which the entire capitalized balance will be amortized on a systematic basis that is consistent with the transfer to the customer of the goods or services to which the asset relates.

Note 6 — Research and Development Expense

Research and development expense consisted of the following items for the years ended December 31:

	2022	2021
Clinical expenses	(56,795)	(10,842)
Non-clinical expenses	(2,802)	(974)
Personnel expense (see Note 8)	(6,752)	(3,363)
Manufacturing costs	(14,850)	(8,338)
Regulatory expenses	(901)	(1,452)
Other R&D costs	(130)	(63)
Total research and development expenses	**(82,230)**	**(25,032)**

Note 7 — Selling, General and Administrative Expenses

Selling, general and administrative expenses consisted of the following items for the years ended December 31:

	2022	2021
Included in selling expenses:		
Commission expense	(2,485)	—
Included in general and administrative expenses:		
Personnel expense (see Note 8)	(5,017)	(1,618)
Travel costs	(430)	(136)
Intellectual property	(1,348)	(708)
Legal costs	(2,176)	(771)
Licenses	—	(28)
Finance and administration	(5,209)	(270)
Transaction costs	(3,021)	—
IT	(25)	(20)
Rent and office services	(165)	(110)
Marketing and communication	(1,269)	(710)
Insurance	(289)	(187)
Depreciation and amortization	(72)	(14)
Commercial costs	(134)	—
Business development	(260)	(135)
Board fees	(69)	(31)
Miscellaneous	(261)	(65)
Total selling, general and administrative expenses	**(22,230)**	**(4,803)**

Note 8 — Personnel Expense

The Group recognized the following personnel expenses within research and development expense and selling, general and administrative expenses for the years ended December 31:

	2022	2021
Wages, salaries and contracted personnel costs	(7,015)	(3,668)
Other employee benefits	(832)	(264)
Share based compensation expense	(3,922)	(1,049)
Total personnel expenses	**(11,769)**	**(4,981)**

Other employee benefit expenses include employee retirement fund contributions. The Company's wholly owned U.S. subsidiary, NewAmsterdam Pharma Corporation, sponsors a defined contribution retirement plan for employees in the United States. During 2022 and 2021, total Group contributions to the defined contribution plan amounted to €66 thousand and €35 thousand, included as other employee benefit expenses.

For the years ended December 31, 2022 and 2021, other employee benefits also include employee health insurance and workers compensation insurance costs amounting to €170 thousand and €75 thousand, employment taxes amounting to €191 thousand and €88 thousand and other miscellaneous expenses amounting to nil and €66 thousand, respectively.

Note 9 — Share Listing Expense

As described in Note 4, the Company issued 13,185,138 shares with a fair value of €126.7 million to former FLAC shareholders, comprised of the fair value of Ordinary Shares that were issued to former

FLAC shareholders of €9.61 per share (translated at the per share price of $9.87 at the Closing Date of FLAC shares). In exchange, the Company received the identifiable net assets held by FLAC, which had a fair value of €66.1 million upon the Closing Date. The excess of the fair value of the equity instruments issued over the fair value of the identified net assets contributed, represents a non-cash expense in accordance with IFRS 2. This one-time expense as a result of the Merger, in the amount of €60.6 million, is recognized as share listing expense presented as part of the financial result within the Consolidated Statement of Profit or Loss and Comprehensive Loss.

Note 10 — Current Prepayments and Other Receivables

Current prepayments and other receivables consisted of the following items as at December 31:

	2022	2021
Prepayments		
Chemistry, Manufacturing and Controls (CMC)	—	21
Non-clinical R&D costs	707	1,111
Clinical other	4,704	349
General and administrative	2,259	11
Total prepayments	7,670	1,492
Value added tax receivable	1,941	4,290
Total prepayments and other receivables	**9,611**	**5,782**

Note 11 — Trade and Other Payables

Trade and other payables consisted of the following items as of December 31:

	2022	2021
Accounts payable	11,113	6,219
Accrued expenses	5,455	375
Value added tax payable	—	2,774
Share based payment liabilities	1,935	458
Total trade and other payables	**18,503**	**9,827**

The share-based payment liabilities are described further in Note 20 for share-based payments.

Note 12 — Income Taxes

Fiscal Unity in the Netherlands

With an effective date of November 21, 2022, NewAmsterdam Pharma Company N.V. formed a fiscal unity with NewAmsterdam Pharma Holding B.V. and NewAmsterdam Pharma B.V. for corporate income tax purposes. A company and its subsidiaries that are part of the fiscal unity are jointly and severally liable for the tax payable by the fiscal unity.

Effective Tax Rate

The table below outlines the reconciliation between the maximum statutory tax rate in 2022 in the Netherlands of 15% for the first €395,000 and 25.8% thereafter (In 2021, this rate was 15% for the first €245.000 and 25% thereafter) and the effective income tax rates for the Company, together with the corresponding amounts, for the years ended December 31:

	2022	2021
Loss before tax	(78,052)	(28,599)
Income tax benefit at statutory tax rate	**20,095**	**7,125**
Difference due to the effects of:		
Movement in unrecognized deferred tax assets resulting from carried forward losses	(20,095)	(7,125)
Income tax expense:	—	—
Effective tax rate:	**0%**	**0%**

Deferred Taxes

Unused tax losses and other credits carried forwards

The Group recognizes a deferred tax asset for unused tax losses, to the extent that it is probable that the deferred tax asset could be utilized against taxable income within the foreseeable future.

As at December 31, 2022, tax losses can be carried forward indefinitely to offset against future taxable income, with utilization of such losses limited to 50% of taxable income in excess of € 1 million in any respective year. As at December 31, 2022 and 2021, the Group had assessed losses amounting to €78.1 million and €28.6 million, respectively. In addition, the Group assumed carry forward losses from the following tax periods, resulting from the fiscal unity of the Company and NewAmsterdam Pharma B.V. as associated with the acquisition of its assets and liabilities:

Year	Tax loss
2012-2013	7,097
2014	11,303
2015	27,255
2016	86,547
2017	1,340
2018	2,303
2019	3,019
2020	6,077
2021	28,599
2022	78,052
	251,592

No deferred tax asset was recognized for these assessed losses as the Group has no products approved for sale, it is not yet probable that the unused tax losses can be utilized against any taxable amounts from the Menarini License, and there are no sources of income in general.

Note 13 — Property, Plant and Equipment

Movements in property, plant and equipment, net were as follows:

	Right of Use Asset	Computer Equipment	Total
(i) Cost			
At 31 December 2020	**—**	**13**	**13**
Additions	172	20	192
At 31 December 2021	**172**	**33**	**205**
(ii) Accumulated depreciation			
At 31 December 2020	**—**	**1**	**1**
Depreciation	10	4	14
At 31 December 2021	**10**	**5**	**15**
(iii) Net book value			
At 31 December 2020	**—**	**12**	**12**
At 31 December 2021	**162**	**28**	**190**

	Right of Use Asset	Computer Equipment	Total
(i) Cost			
At 31 December 2021	**172**	**33**	**205**
Additions	—	13	13
At 31 December 2022	**172**	**46**	**218**
(ii) Accumulated depreciation			
At 31 December 2021	**10**	**5**	**15**
Depreciation	64	8	72
FX	(15)	2	(13)
At 31 December 2022	**59**	**15**	**74**
(iii) Net book value			
At 31 December 2021	**162**	**28**	**190**
At 31 December 2022	**113**	**31**	**144**

The Group leases office premises in Florida. Refer to Note 22 for lease liability details related to the right of use asset.

Note 14 — Loans Receivable

Movements in loans receivable were as follows:

	Loans Receivable
At January 1, 2021	—
Loan provided	709
Accrued finance expense	9
At December 31, 2021	**718**
Accrued finance expense	10
Repayment of loan	(728)
At December 31, 2022	**—**

On June 28, 2021, NewAmsterdam loaned its chief executive officer, M. Davidson, €709 thousand for the payment of a purchase price related to issued depository receipts issued by the Stichting Administratiekantoor EPNAP ("**STAK EPNAP**") to the M. Davidson. NewAmsterdam Pharma, M. Davidson and STAK EPNAP entered into a founder depository receipt award agreement. Interest accrued on the principal amount of the loan at a rate per annum of 2.75%. The interest accrued from day to day and was added to the principal amount of the loan as from the date that the loan was made available up to the last business day of the loan term.

On July 19, 2022, M. Davidson, repaid the entire amount of the loan facility of €709 thousand, including outstanding unpaid interest of € 19 thousand, for a total of € 728 thousand.

Note 15 — Intangible Assets

On April 9, 2020, NewAmsterdam Pharma entered into a purchase agreement with Amgen (the "**2020 SPA**"), to acquire all of the outstanding share capital of NewAmsterdam Pharma B.V. (formerly Dezima Pharma B.V.), a company whose principal activity is to develop compounds that treat cardiovascular disease related to dyslipidemia. The principal reason for this acquisition was to secure the intellectual property, licensing and know-how of the patented drug Obicetrapib and the in-process research and development. NewAmsterdam Pharma paid consideration of €1 for the IPR&D asset and could potentially make an additional contingent payment depending on future exit events (if they occur) as further described below. In connection with the 2020 SPA, NewAmsterdam Pharma and Amgen entered into a profit right and waiver agreement with MTPC (the "**Profit Right Agreement**") in consideration for the waiver of certain rights held by MTPC prior to the Dezima transaction.

The aggregate contingent consideration to be paid to Amgen and MTPC would become payable upon a traditional underwritten public offering or an exit event, as defined in the 2020 SPA. The profit right shall lapse if the IPO share right is exercised. The IPO share right shall lapse if, as a result of one or more exit events, the profit right is exercised and all of the assets related IPR&D are sold, leased, transferred, licensed, or otherwise disposed of, or there are no remaining shares. Further, upon an IPO, Amgen would also have the right to repurchase all of the outstanding shares of NewAmsterdam Pharma B.V. at a certain specified price. In addition, Amgen and MTPC were granted rights to match certain major corporate transactions ("**Matching Rights**"). The transactions contemplated by the Business Combination Agreement (as defined in Note 4) qualified as an exit event pursuant to the 2020 SPA but were not subject to Matching Rights. As a result, in connection with the Business Combination and pursuant to side letters entered into by the parties, Amgen and MTPC each received their respective profit right payments in the form of Ordinary Shares, in the amount of 4,910,000 Ordinary Shares and 3,746,330 Ordinary Shares to Amgen and MTPC, respectively, prior to the consummation of the Business Combination. Based on the price of €9.61 per Ordinary Share at the Closing Date, the issuance of an aggregate of 8,656,330 Ordinary Shares increased equity by €83.2 million (see Note 19). Management determined the issuance of Ordinary Shares to Amgen and MTPC as an exit event resulting in additional contingent consideration paid for the IPR&D asset. As such, the IPR&D asset was subsequently recognized at the fair value of Ordinary Shares issued of €83.2 million.

Upon the issuance of Ordinary Shares to Amgen and MTPC, all rights of Amgen and MTPC under the 2020 SPA and the Profit Right Agreement, respectively, were extinguished. At December 31, 2022, management determined that the contingent consideration no longer exists as a result of the equity

issuance of Ordinary Shares having extinguished all rights previously held by Amgen and MTPC upon acquisition.

Note 16 — Financial Risk Management

The Group's principal financial liabilities consist of trade and other payables, derivative warrant liabilities and derivative earnout liability. The main purpose of these financial liabilities is to finance the Group's day-to-day operations. The Group's financial assets consist of prepayments and other receivables and cash, and had a loan receivable balance in 2021, that are derived from the Group's operating activities and funding.

The Group is exposed to market risk, credit risk and liquidity risk. The Company's senior management oversees the management of these risks. The Board reviews and agrees policies for managing each of these risks, which are summarized below.

Market Risk

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices. Market risk comprises interest rate risk, foreign currency risk and other price risks.

The sensitivity analyses in the following sections relate to the position as of December 31, 2022 and 2021.

Interest rate risk

The only variable interest-bearing financial instruments are cash. Changes in interest rates may cause variations in interest income and expense resulting from short-term interest-bearing assets. 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 current financial assets. Currently the interest rate exposure is not hedged.

Interest rate sensitivity

The following table demonstrates the sensitivity to a reasonably possible change in interest rates on that portion of financial assets affected. With all other variables held constant, the Company's profit or loss before tax/equity is affected through the impact on floating rate borrowings, as follows:

	Increase / (decrease) in basis points	Increase/ (decrease) on profit before tax/ Equity
2021		
Euro	100	(380)
Euro	(100)	380
U.S. Dollar	100	(150)
U.S. Dollar	(100)	150
2022		
Euro	100	(1,517)
Euro	(100)	1,517
U.S. Dollar	100	(2,867)
U.S. Dollar	(100)	2,867

Foreign currency risk

Foreign currency risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in foreign exchange rates. The Group's exposure to the risk of changes in foreign exchange rates relates primarily to cash, and trade and other payables denominated in currencies other than the functional currency of the Group. As of December 31, 2022 and at December 31, 2021, the Group's net exposure to foreign currency risk amounts to €268.2 million and €15.9 million, respectively, primarily arising from exposure to the U.S. Dollar.

The Group partly manages its foreign currency risk by selectively holding foreign currency in its cash to offset foreign currency exposures from liabilities and trade and other payables denominated in varying foreign currencies. The Group plans to use this cash to settle future expenses it expects to incur in those foreign currencies.

Due to proceeds received from the Merger with FLAC and PIPE Financing that were denominated in U.S. dollar, the Group has a significant U.S. dollar balance on its statements of financial position held as cash. In 2022, the Group recognized significant foreign exchange losses as the Group´s functional currency is Euro but hold significant U.S. dollar amounts.

Foreign currency sensitivity

The Group is mainly exposed to the currency of U.S. Dollar, British Pound Sterling and Japanese Yen. The following table demonstrates the sensitivity to a possible change in exchange rates against the Euro with all other variables held constant. Additional sensitivity changes to the indicated currencies are expected to be approximately proportionate. The table shows the effect on the Group's profit or loss before tax (due to changes in the value of monetary assets and liabilities). The Group's exposure to foreign currency changes for all other currencies is not material. There is no impact to equity other than to accumulated deficit and no impact to other comprehensive income.

Change in foreign exchange rate against Euro	Effect on profit / (loss) before tax	
	10% depreciation	10% appreciation
2021		
British Pound Sterling	(9)	15
Canadian Dollar	—	1
Japanese Yen	(1)	1
U.S. Dollar	(1,360)	1,843
2022		
British Pound Sterling	(55)	67
Japanese Yen	34	(41)
U.S. Dollar	(24,361)	29,775

Other Market Price Risk

As a result of the Merger with FLAC, the Company has derivative warrant liabilities and a derivative earnout liability which are measured at FVTPL (see Note 17). At December 31, 2022, derivative warrant liabilities and derivative earnout liability amount to €3.9 million and €7.1 million, respectively.

The following table demonstrates the sensitivity to a reasonably possible change in share prices on that portion of financial liabilities affected, being the key input. Volatility in the price of the Ordinary Shares has no material impact on the fair value of the financial liabilities. With all other variables held constant, including the expected volatility in the price of the Ordinary Shares on Nasdaq, the Company's profit or loss before tax/equity is affected through the impact on market prices, as follows:

	% Increase / (decrease) in share price (NAMS / NAMSW)	Increase/ (decrease) in profit or loss before tax/equity
2022		
Derivative warrant liabilities (under NAMSW)	15	(583)
Derivative warrant liabilities (under NAMSW)	(15)	583
Derivative earnout liability (under NAMS)	15	(1,058)
Derivative earnout liability (under NAMS)	(15)	1,058

Credit Risk

Credit risk is the risk that a counterparty will not meet its obligations under a financial instrument or customer contract, leading to a financial loss. The Group is exposed to credit risk primarily from its treasury activities, including deposits with banks and financial institutions and has limited credit risk

exposure from its operating activities. The Group holds available cash in bank accounts with banks which have investment grade credit ratings. Management periodically reviews the creditworthiness of the banks with which it holds assets.

The Group provided an interest-bearing secured loan to the Chief Executive Officer which has been fully repaid as of December 31, 2022. Refer to Note 14 for details surrounding repayment.

The Group performs research and development activities and does not yet have any sales. Therefore, the Group is able to reclaim Value Added Tax ("**VAT**") which is recoverable from tax authorities. Management periodically reviews the recoverability of the balance of input value added tax and believes it is fully recoverable.

The Group's maximum exposure to credit risk for the components of the consolidated statement of financial position at December 31, 2022 and 2021, is the carrying amount as illustrated in Note 10 (excluding prepayments) and Note 11.

Liquidity Risk

The Company monitors its risk to a shortage of funds using forecasting planning tools. The Group's objective is to maintain a sufficient level of funding in order to continue its research and development activities and capital and financing obligations. The Group 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 liquidity are obtained through licensing arrangements and financing proceeds. The Company believes that it has sufficient liquidity as a result of the upfront fee received from the Menarini License (see Note 5) and the recent equity funding from the Merger with FLAC which had both occurred in the current reporting period (see Note 4), resulting in the cash balance of €438.5 million at December 31, 2022 (see Note 18).

Maturity profile

The table below summarizes the maturity profile of the Group's financial liabilities based on contractual undiscounted payments. Amounts disclosed are based on spot rates at the reporting date. Payments related to foreign currency are included at the exchange rates applicable as at December 31, 2022 and 2021.

	On demand	Less than 3 months	3 - 12 months	More than 1 year	Total
At December 31, 2021					
Trade and other payables	—	5,715	880	—	6,595
Value added tax payable	—	2,774	—	—	2,774
Share based payment liabilities	458	—	—	—	458
Lease liability	—	13	40	111	164
Total financial liabilities	458	8,502	920	111	9,991

	On demand	Less than 3 months	3 - 12 months	More than 1 year	Total
At December 31, 2022					
Trade and other payables	—	16,448	92	28	16,568
Share based payment liabilities	1,935	—	—	—	1,935
Lease liability	—	15	63	40	118
Derivative warrant liabilities	3,888	—	—	—	3,888
Derivative earnout liability	—	—	—	7,053	7,053
Total financial liabilities	5,823	16,463	155	7,121	29,562

Capital Management

For the purpose of the Company's capital management, capital includes issued share capital, share premium contribution and all other equity reserves attributable to the equity holders of the Company. The primary objective of the Company's capital management is to ensure that it will be able to continue as a going concern. The current cash on hand and the anticipated research activities are the most important parameters in assessing the capital structure. The Company monitors capital management to ensure that it meets its financial needs to achieve its business objectives while maintaining its solvency.

Note 17 — Financial Assets and Liabilities Fair Value

Financial liabilities consist of trade and other payables, lease liability, derivative warrant liabilities and derivative earnout liability.

The carrying amount of cash, trade and other payables approximate their fair value due to their short-term nature. The fair values of these financial assets and liabilities are included at the amount at which the instrument could be exchanged in a current transaction between willing parties, other than in a forced or liquidation sale. Lease liabilities are measured at amortized cost based on the present value of the contractual payments due to the lessor over the lease term.

Derivative Warrant Liabilities

Immediately following the Merger mentioned in Note 4, each outstanding warrant to purchase a Class A ordinary share, par value $0.0001 per share, of FLAC became a warrant to purchase one Ordinary Share, on substantially the same terms as were in effect immediately prior to the Closing Date which resulted in the issuance of 167,000 Private Placement Warrants and 4,600,000 Public Warrants (collectively, the **"Warrants"**) and were considered part of the net assets of FLAC at the time of the

Merger. The Company assumed and continues to hold these warrants on the same terms as before (to the extent applicable). No new warrants were issued and no existing Warrants were exercised or redeemed from the Closing Date to December 31, 2022. At December 31, 2022, the Group had 4,600,000 and 167,000 Public Warrants and Private Placement Warrants outstanding, respectively.

Both Private Placement Warrants and Public Warrants entitle the holder to convert each warrant into one Ordinary Share of the Company of €0.12 par value at an exercise price of $11.50 per Ordinary Share at any time commencing 30 days after the date after the Closing Date.

Once exercisable, the Company may call the Warrants for redemption if the closing market price of Ordinary Shares equals or exceeds $18.00 per share for any 20 trading days within a 30-trading day period ending on the third trading day prior to the date on which notice of the redemption is given to the warrant holders (the "**Reference Value**"). The Company may redeem the outstanding Warrants if the Reference Value equals or exceeds $10.00 per share (as adjusted for share subdivisions, share dividends, reorganizations, recapitalizations and the like) on the trading day prior to the date on which notice of the redemption is given to the warrant holders. The terms of the Private Placement Warrants are identical to the Public Warrants except if the Reference Value is less than $18.00 per share, the Private Placement Warrants must also be concurrently called for redemption on the same terms as the outstanding Public Warrants.

Until Warrant holders acquire the Ordinary Shares upon exercise of such Warrants, they will have no voting or economic rights. The Warrants will expire on November 23, 2027, five years after the date after the Closing Date, or earlier upon redemption or liquidation in accordance with their terms.

As there are no elements in the Warrants that give the Company the possibility to prevent the warrant owners to convert their warrants within 12 months the Company has classified the derivative warrant liabilities as a current liability.

The fair value of the Warrants increased from $0.80 per warrant as of the Closing Date to $0.87 per warrant at December 31, 2022. Consequently, for the year ended December 31, 2022, the Group has recognized a charge of €0.3 million in profit or loss, which has been presented as a change in the fair value of derivative warrant liabilities under fair value change – derivative earnout and warrants expense.

Derivative Earnout Liability

As mentioned in Note 4, the Business Combination Agreement contemplates the issuance of Earnout Shares, totaling 1,886,137 Ordinary Shares, contingent upon the achievement of a development milestone. Of the total Earnout Shares 1,725,358 Earnout Shares are currently allocated to Participating Shareholders. The development milestone consists of achievement and public announcement of Positive Phase 3 Data (as defined in the Business Combination Agreement) for each of the Company's BROADWAY clinical trial and BROOKLYN clinical trial at any time during the period beginning on the day prior to the Closing Date and ending on the date that is five years after the Closing Date (the "**Earnout Period**"). As the development milestone has not yet been achieved, no Earnout Shares have been issued as of December 31, 2022, and no Earnout Shares will be issuable if the applicable milestone is not achieved within the Earnout Period.

At the closing of the Merger, the fair value of the Earnout Shares allocated to Participating

Shareholders was €6.4 million. The financial liability was remeasured at December 31, 2022 which resulted in a charge of €0.7 million in profit or loss, which has been presented as a change in the fair value of derivative warrant liabilities under fair value change – derivative earnout and warrants expense.

Fair value measurements

The financial liability for the derivative warrants is accounted for at fair value through profit or loss. The Public Warrants are considered liquid and are actively listed on Nasdaq and have been measured at fair value using the quoted price (Level 1).

The Private Placement Warrants have been measured at fair value using inputs other than quoted prices included in Level 1 that are observable for the liability (Level 2), since the terms of the Private Placement Warrants are considered to be nearly identical to the Public Warrants, and the Public Warrants have an observable price in the active market. For these reasons, the measurement of the Private Placement Warrants can be indirectly derived from the quoted price of the Public Warrants.

The estimated fair value of the Earnout Shares to Participating Shareholders was determined using Level 3 inputs, other than the Company's share price as a Level 1 input, as no observable market inputs were available. The Earnout Shares allocated to Participating Shareholders have been measured at fair value using a Black-Scholes pricing model. Inputs to the fair value of the derivative earnout liability are as follows:

	December 31, 2022
Share value (USD)	10.90
Volatility (%)	33% - 35%
Expected Range of milestone completion (years)	1.33 - 1.67
Probability of milestone completion	40%
Dividend yield	0%
Risk-free rate	4.50% - 4.60%
Strike price (USD)	0.00

The initial recognition of the Earnout Shares allocated to Participating Shareholders included the same Level 3 inputs except for the share value which was €9.61 per share at the Closing Date (translated at the per share price of $9.87 at the Closing Date).

The assumptions used to determine the fair value of the Earnout Shares allocated to Participating Shareholders represent management’s best estimates. The Group estimates the volatility of its Earnout Shares allocated to Participating Shareholders from historical volatility of selected peer companies’ common stock that matches the expected timing of the milestone completion date. The expected timing of the milestone completion date is based on management’s estimation and relevant industry targets. The dividend rate is based on the historical rate, which the Company anticipates will remain at zero.

Given the assumed zero dividend rate and the fact that no strike price exists that would have led to any volatility measure relative to the Company's share price, the fair value of the Earnout Shares allocated to Participating Shareholders resulting from the Black-Scholes pricing model is driven by the Company’s closing share price as a Level 1 input and the probability of milestone completion as a Level

3 input. As management's judgment of the probability of milestone completion remained constant during the period, the change in fair value resulted from the Company's price per share between the valuations performed at the Closing Date and at December 31, 2022. The resulting per share fair value of the Earnout Shares allocated to Participating Shareholders is €4.09 at December 31, 2022, compared to a per share fair value of €3.84 at the Closing Date.

The following table summarizes the results of changes to the probability of the milestone completion, as being the significant unobservable Level 3 input and key sensitive parameter used in the valuation model on the fair value of the allocated to Participating Shareholders:

	Increase/ (decrease) on profit before tax/equity (in €'000s)
Changes to parameters	
Increase in probability of milestone achievement by 20%	(3,526)
Decrease in probability of milestone achievement by 20%	3,526

Refer to Note 16 for a sensitivity analysis over the change in the Company's share prices on the fair value of the Earnout Shares allocated to Participating Shareholders, with all other variables held constant. The derivative earnout liability, which is classified as Level 3, was initially recognized on the Closing Date during the year. The only change during the year related to its remeasurement which resulted in an increase to the liability and a corresponding charge of €0.7 million in profit or loss, which has been presented as a change in the fair value of derivative earnout liability under fair value change - earnout and warrants expense.

The following table shows the carrying amounts of the financial liabilities measured at fair value through profit and loss on a recurring basis:

	Level 1	**Level 2**	**Level 3**	**Total**
Liabilities measured at FVTPL				
Derivative warrant liability (Public Warrants)	3,752	—	—	3,752
Derivative warrant liability (Private Placement Warrants)	—	136	—	136
Derivative earnout liability	—	—	7,053	7,053
Total financial liabilities	**3,752**	**136**	**7,053**	**10,941**

Reconciliation of movements of liabilities to cash flows arising from financing activities

	Lease liability	Derivative earnout liability	Derivative warrant liabilities	Total liabilities from financing activities
At January 1, 2022	**164**	**—**	**—**	**164**
Principal paid on lease liabilities	(56)	—	—	(56)
Interest paid on lease liabilities	(9)	—	—	(9)
Total changes from financing cash flows	**(65)**	—	—	**(65)**
Effect of changes in foreign exchange rates	10	(243)	(137)	(370)
Interest charges	9	—	—	9
Acquired at Closing Date	—	6,633	3,712	10,345
Change in fair value	—	663	313	976
Total liability-related charges	**19**	**7,053**	**3,888**	**10,960**
At December 31, 2022	**118**	**7,053**	**3,888**	**11,059**

	Lease liability	Derivative earnout liability	Derivative warrant liabilities	Total liabilities from financing activities
At January 1, 2021	**—**	**—**	**—**	—
Principal paid on lease liabilities	(8)	—	—	(8)
Interest paid on lease liabilities	(2)	—	—	(2)
Total changes from financing cash flows	**(10)**	—	—	**(10)**
Interest charges	2	—	—	2
Capital increases	172	—	—	172
Total liability-related charges	**174**	**—**	**—**	**174**
At December 31, 2021	**164**	**—**	**—**	**164**

Note 18 — Cash

Cash comprise entirely of bank balances and consisted of the following items as at December 31:

	2022	2021
Cash at banks	438,522	53,092
Cash	**438,522**	**53,092**

The cash at banks is at full disposal of the Company.

Note 19 — Share Capital and Share Premium

The following table details the total share capital and share premium of the Group as at December 31, 2022 and 2021:

	Shares	Price per share (in €)	Share Capital (in €'000)	Share Premium (in €'000)	Total (in €'000)
At January 1, 2021	**5,000,000**	**0.01**	**50**	**2,450**	**2,500**
January 2021 Conversion of convertible debt[(1)]	1,111,115	0.01	11	11,656	11,667
January 2021 Equity contributions (Series A - Tranche I)[(1)]	4,928,613	0.01	49	68,951	69,000
July 2021 Issuance of non-voting shares	285,714	0.01	3	706	709
At December 31, 2021[(2)]	**11,325,442**	**0.01**	**113**	**83,763**	**83,876**
February 18, 2022 Equity contribution (Series A - Tranche II)[(3)]	5,691,430	0.01	57	79,623	79,680
At November 22, 2022, prior to exchange	**17,016,872**	**0.01**	**170**	**163,386**	**163,556**
November 22, 2022 Elimination old shares (NewAmsterdam Pharma shareholders)[(4)]	(17,016,872)	0.01	(170)	(163,386)	(163,556)
November 22, 2022 Share capital increase on conversion (NewAmsterdam Pharma shareholders)[(4)]	36,258,312	0.12	4,351	159,205	163,556
November 22, 2022 Equity contribution (FLAC shareholders)[(5)]	13,185,138	0.12	1,582	125,084	126,666
November 22, 2022 Equity contribution (PIPE financing)[(6)]	23,460,000	0.12	2,815	225,528	228,343
November 22, 2022 Equity contribution (Amgen & MTPC shareholders)[(7)]	8,656,330	0.12	1,039	82,121	83,160
November 22, 2022 Transaction costs on issue[(5)] of shares	—	—	—	(2,534)	(2,534)
At December 31, 2022[(8)]	**81,559,780**	**0.12**	**9,787**	**589,404**	**599,191**

(1) On January 7, 2021, NewAmsterdam Pharma closed a funding round to raise up to €160 million in equity financing, set to occur in two tranches. The first tranche of €69 million occurred upon an initial closing on January 7, 2021 for the issue of 4,928,613 Series A preferred shares on the same date. In connection with the funding round of the first tranche, €11.7 million in outstanding principal and unpaid interest of convertible debt was converted on the same date of the first tranche into 1,111,155 Series A preferred shares.

(2) At December 31, 2021, the share capital of NewAmsterdam Pharma amounted to €113 thousand, divided into 2,500,000 voting ordinary shares, 2,785,714 non-voting ordinary shares and 6,039,728 Series A preferred shares, each with a nominal value of €0.12 per share.

(3) On February 18, 2022, NewAmsterdam Pharma received the second tranche financing of €79.7 million for the issuance of 5,691,430 Series A preferred shares, leading to increases in the share capital and share premium amounting to €57 thousand and €79.6 million, respectively, as a result of attainment of certain milestone tranche conditions (the "**Milestone Closing**"), namely: at least

50% LDL lowering in the ongoing obicetrapib and ezetimibe Phase 2 combination trial; the hiring of a full-time chief business officer; and confirmation by the FDA that no CVOT would be required for regulatory approval in the United States. After achieving the first two of these milestones, NewAmsterdam Pharma proceeded with the Milestone Closing as permitted by the terms of the Series A Subscription Agreement. Because the Milestone Closing occurred without having achieved all of the milestones, NewAmsterdam Pharma was obligated to pursue certain strategic transactions, including a business combination with a special purpose acquisition company.

(4) As described in Note 1 and Note 4, the Company was incorporated in June 2022 with a share capital of €0.12. On November 22, 2022, pursuant to the Business Combination Agreement, NewAmsterdam Pharma shareholders exchanged their interest for Ordinary Shares in the share capital of the Company in accordance with an exchange ratio defined in the Business Combination Agreement of approximately 2.13. Consequently, following this internal reorganization, 17,016,872 NewAmsterdam Pharma shares of €0.01 par value were exchanged for 36,258,312 Ordinary Shares, €0.12 par value per share. As such, share capital increased by €4.2 million and the share premium decreased by the same amount.

(5) On November 22, 2022, each ordinary share of FLAC was canceled and exchanged for one Ordinary Share resulting in the issuance of 13,185,138 Ordinary Shares, thereby increasing share capital and share premium by €1.6 million and €125.1 million, respectively, which includes the impact of equity related to the IFRS 2 listing charge for €60.6 million (See Note 9) and, inclusive of the issuance of new Ordinary Shares from the PIPE Financing, the deduction of the net of the transaction costs on issuance of new Ordinary Shares amounting to €2.5 million.

(6) In connection with the Merger, the Company issued 23,460,000 Ordinary Shares to existing shareholders of NewAmsterdam Pharma, FLAC and other new investors through a PIPE Financing, at a price of $10.00 per Ordinary Share for an aggregate of $234.6 million in proceeds on the Closing Date. The issuance of the 23,460,000 Ordinary Shares increased share capital and share premium by €2.8 million and €225.5 million, respectively.

(7) As described in Note 4 and Note 15, the Company also issued 4,910,000 Ordinary Shares and 3,746,330 Ordinary Shares to Amgen and MTPC, respectively, each with a nominal value of €0.12 per share, in order to settle all rights of Amgen and MTPC under the 2020 SPA and Profit Right Agreement, respectively. The issuance of an aggregate of 8,656,330 Ordinary Shares increased share capital and share premium by €1.0 million and €82.1 million, respectively.

(8) Upon completing the Business Combination, the Company had 81,559,780 Ordinary Shares outstanding with a par value of €0.12 per share, resulting in a share capital of €9.8 million. As of December 31, 2022, the total number of Ordinary Shares outstanding was 81,559,780 with a par value of €0.12 per share.

Note 20 — Share-Based Payments

The Company has two Share-based payment plans and one restricted share award in place as at December 31, 2022:

- The Company's Long-Term Incentive Plan (the "**Plan**"), which also includes restricted stock units;
- the Company's Rollover Option Plan (the "**Rollover Plan**," together with the Plan, the "**Plans**"); and
- Chief Executive Officer Restricted Share Award.

Long Term Incentive Plans

In November 2022, the Company adopted Plans in connection with the Business Combination to replace the Prior LTIP (as defined below). The Plans are equity-settled, and the Company may grant various forms of equity awards, including the granting of options to purchase Ordinary Shares ("**Company Options**"), pursuant to the Plans.

Each option of NewAmsterdam Pharma granted under the Prior LTIP ("**NewAmsterdam Pharma Options**") outstanding immediately prior to the consummation of the Exchange remained outstanding and, to the extent unvested, continued to vest in accordance with its applicable terms, and at the time of the Exchange, such options became options to purchase, and will when exercised be settled in Ordinary Shares under the Plans. Additionally, the exercise price of each converted option has been determined by dividing the exercise price per share (or depository receipt for a share) of each option to purchase shares (or depository receipts for shares) of NewAmsterdam Pharma by an exchange ratio of approximately 2.13.

Term and Vesting Period

The contractual term is 10 years from grant date for options granted. Each new option granted in 2022 under the Plans has a four-year vesting period with 1/48 vesting on each one-month anniversary of the grant date.

In the case of a participant who voluntarily leaves and therefore ceases to be an eligible participant ("**Good Leaver**"), all unvested options will lapse and all vested options that have not yet been exercised or settled must be exercised or settled within 3 months after the Participant became a Good Leaver.

If long-term incentive awards are granted in exchange for outstanding options under the Plans in connection with a change of control and the Board has determined that such awards are sufficiently equivalent to the outstanding options concerned, then such outstanding options shall be cancelled and terminated upon the replacement awards being granted to the participants concerned. If this is not the case, then such options shall immediately vest in full, unless the Board decides otherwise.

Prior to the modification on November 22, 2022, NewAmsterdam Pharma introduced a long-term incentive plan (the "**Prior LTIP**") for employees, officers, and other service providers in July 2021. Under this equity-settled plan, NewAmsterdam Pharma granted options on Depositary Receipts ("**DRs**") relating to non-voting ordinary shares and options on non-voting ordinary shares. On July 8, 2021, NewAmsterdam Pharma granted 262,857 Pre-Series A options, 887,116 First Tranche Options, and 814,312 Second Tranche Options. Each option had a four-year vesting period with 25% vesting after one year and the remaining 75% vesting in equal installments over the next following three years. All options under the Prior LTIP were issued with the same terms with the exception of the Second Tranche Options, which were subject to the following two additional vesting conditions: (i) the Milestone Closing (i.e., the closing of the second tranche of the Series A financing round) having occurred, provided that the Milestone Closing occurs prior to June 1, 2022; and (ii) the Participant's employment, management, or advisory agreement having continued uninterrupted through the date of the Milestone Closing. These additional non-market vesting conditions were met in 2022.

Modifications of Options During the Year

The options issued under the Prior LTIP have been converted into 4,185,360 options issued under the Plans over Ordinary Shares in the Company in connection with the Business Combination Agreement.

The changes related to the NewAmsterdam Pharma Options have been treated as a modification because the Business Combination Agreement outlines that the new award replaces a canceled award; and so it is treated as if the original award had been modified. Each replacement option (i.e., Company

Option) shall be subject to the same terms and conditions (including applicable vesting, expiration and forfeiture provisions) that applied to the NewAmsterdam Pharma Option immediately prior to the closing of the Business Combination. Since the change was structured to preserve the value of the NewAmsterdam Pharma Options, the total fair value of the replacement options granted to an employee is the same as the fair value of the NewAmsterdam Pharma Option held immediately before the closing of the transaction. Therefore, no incremental fair value has been granted in relation to the replacement of the NewAmsterdam Pharma Options with Company Options, and the grant date fair value of the original NewAmsterdam Pharma Options will therefore continue to be charged over the original vesting period.

In total, 1,964,286 NewAmsterdam Pharma Options with an exercise price of €2.48 were outstanding as of December 31, 2021 and as of the date prior to the Exchange. At the time of the Exchange, these were converted into 4,185,360 Company Options with an exercise price of €1.16392. The number of options and the exercise price presented as comparative information for 2021 in the tables below have been updated to reflect this conversion in 2022. In addition, on November 22, 2022, the Company granted 6,961,501 Company Options under the Plan.

The changes in the number of options outstanding related to Ordinary Shares and their related weighted average exercise prices are as follows:

	2022		2021	
	Weighted average exercise price	**Number of options**	**Weighted average exercise price**	**Number of options[(1)]**
Outstanding as at January 1	**€ 1.16**	**4,185,360**	**—**	**—**
Granted during the year	$ 10.00	6,961,501	€ 1.16	4,185,360
Forfeited during the year	—	—	—	—
Outstanding as at December 31	€ 6.52	**11,146,861**	**1.16**	**4,185,360**

(1) On November 22, 2022, the NewAmsterdam Pharma Options outstanding of 1,964,286 were exchanged for 4,185,360 Company Options using an exchange ratio of approximately 2.13. The weighted average exercise price was also re-stated from €2.48 to €1.16392 based on the same exchange ratio. The 2021 amounts and the opening balance as at January 1, 2022, have been restated to reflect this conversion.

As at December 31, 2022, 2,837,865 of the outstanding Company Options are exercisable. The Company Options granted on November 22, 2022 have an exercise price of $10.00 per option and will expire on November 22, 2032. The options outstanding as of December 31, 2022 and 2021 have a weighted average remaining contractual life of 9.4 years and 9.5 years, respectively.

	2022		2021	
Expiry date	**Exercise Price**	**Number of options**	**Exercise Price**	**Number of options**
July 6, 2031	€ 1.16	4,185,360	€ 1.16	4,185,360
November 22, 2032	$ 10.00	6,961,501	—	—
Outstanding as at December 31	€ 6.52	**11,146,861**	**1.16**	**4,185,360**

Fair Value of Options Granted

The Black-Scholes option pricing formula has been applied for measuring the fair value of the

options granted. The assumptions used to determine the fair value of the options represent management's best estimates. These estimates involve inherent uncertainties and the application of management's judgment, specifically as it relates to share value prior to the Merger, volatility and expected life. The weighted average fair values and the inputs (ranges) used in the measurement of the fair values of these equity-settled options at the date of grant are summarized below:

	2022	2021
Share value (EUR)	9.61	2.48
Option exercise price (EUR)	9.73	2.48
Volatility (%)	38% - 42%	42% - 44%
Expected life (years)	5.0 - 7.0	5.0 - 6.9
Dividend yield	0%	0%
Risk-free rate	3.88% - 3.93%	(0.62%) - (0.58%)
Fair value per option (EUR)	4.20	0.91 - 0.98

The expected option life is based on management's best estimate of when the options will be exercised. Expected volatility is estimated by considering historical average share price volatility of a group of comparable companies over a period before the grant date being equal to the expected option life. The expected dividend rate is zero as the Company currently has no history or expectation of declaring dividends on its ordinary shares. For the options granted in 2021 with an exercise price denominated in euro, the risk-free interest rate is estimated based on the continuous yield on triple A-rated, zero-coupon government bonds in the Eurozone with a term to maturity comparable to the (remaining) expected option life. For the options granted in 2022 with an exercise price denominated in U.S. dollars, the risk-free interest rate is based upon the U.S. Treasury yield curve in effect at the time of grant, with a term that approximates the expected life of the option.

For the options granted in 2022, the fair value of the Ordinary Shares is equal to the closing share price at the grant date. For the 1,964,286 NewAmsterdam Pharma Options granted in 2021 with an exercise price of €2.48, the fair value of the underlying ordinary shares in NewAmsterdam Pharma (the share value in table above) was estimated in the absence of a public market for the company's equity instruments. NewAmsterdam Pharma relied on an option pricing method ("**OPM**") to determine fair value of the ordinary shares. The OPM allocates the overall equity value to the various share classes based on differences in liquidation preferences and participation rights. After the value of the ordinary shares is determined, a discount for lack of marketability ("**DLOM**") of 15% is applied to arrive at fair value of the underlying ordinary shares. A DLOM is applied in order to reflect the lack of a recognized market for a privately held interest and the fact that equity interest may not be readily transferrable. A market participant purchasing this equity instrument would recognize this illiquidity associated with the equity instrument which would reduce the overall fair market value.

Share-Based Payment Expenses Recognized for Options Granted

The fair value of the options is expensed over the relevant vesting periods using the graded vesting method, based on management's estimate of the number of options that will eventually vest. For the years ended December 31, 2022 and 2021, the total share-based payment expense recognized for the equity-settled options amounted to €3.922 million and €1.049 million, respectively.

In addition, during the years ended December 31, 2022 and 2021, the Company recognized €1.612 million and €43 thousand as expenses for the employer social security contributions expected to be

payable related to these options. The corresponding liability as of December 31, 2022 and 2021 amounts to €1.655 million and €43 thousand, respectively.

Restricted Stock Units ("RSUs")

As a result of the Business Combination Agreement, the Company has currently allocated 160,778 Earnout Shares to grant to Participating Optionholders if and when a certain clinical development milestone is achieved during the earnout period. These Earnout Shares will be delivered in the form of awards of RSUs granted pursuant to the Plan to such Participating Optionholders who are at the time of achievement of such milestone still providing services to the Company or its subsidiaries.

The development milestone consists of the achievement and public announcement of Positive Phase 3 Data for each of NewAmsterdam Pharma's BROADWAY clinical trial and BROOKLYN clinical trial at any time during the period beginning on November 22, 2022 and ending on the date that is five years after such date. As a result, no Earnout Shares will be issuable if the applicable milestone is not achieved within five years of the Merger. If the clinical development milestone is not achieved during the Earnout Period, but a Participating Optionholder has completed their service requirement, they will not be considered vested in the RSUs.

There is no impact on these financial statements with respect to the Participating Optionholders' awards due to the uncertainty of achieving the clinical development milestone. Refer to Note 17 regarding the financial statement impact of the Earnout Shares allocated to Participating Shareholders.

Chief Executive Officer Restricted Share Award

In July 2021, NewAmsterdam Pharma entered into an arrangement and issued 285,714 non-voting ordinary shares to a foundation (**"STAK EPNAP"**) at an aggregate issue price of €708,571 for which Depository Receipts ("**Founder DRs**") were agreed to be issued by STAK EPNAP to NewAmsterdam Pharma's chief executive officer, M. Davidson, under the Prior LTIP. The vesting and contractual terms for this transaction align with other DRs issued under the Prior LTIP in 2021 that have been previously disclosed, except as noted below.

NewAmsterdam Pharma provided a loan facility to M. Davidson to pay the purchase price of the Founder DRs subject to the terms and conditions of the loan agreement. On July 19, 2022, M. Davidson repaid the entire outstanding principal amount and unpaid interest.

The Company does not have an obligation to repurchase any vested Founder DRs or otherwise settle vested DRs in cash or repurchase any vested DRs. This element of the Founder DR award is therefore accounted for as an equity-settled share-based payment transaction. M. Davidson paid the fair market value of the underlying ordinary shares in the Company at the grant date, each €2.48 per share. Accordingly, the total fair value of these equity-settled share-based payment awards amounts to nil and there will be no expenses recognized in the income statement related to these investments.

In connection with the award arrangement, if M. Davidson leaves NewAmsterdam Pharma, all unvested Founder DRs will be cancelled automatically, with simultaneous cancellation of the underlying shares, and against payment by the Company to the participant of the lower of the (i) the purchase price paid and (ii) the fair market value. As the Founder DRs were delivered immediately on receipt for consideration paid by M. Davidson but remain subject to ongoing vesting conditions, to reflect the consideration paid and the potential that the Ordinary Shares may be repurchased, the Company has

recognized the consideration as a financial liability until the awards have vested, at which time it will be reclassified to equity provided that M. Davidson remains with the Group. This liability is measured at the lower of the price paid for the Founder DRs and their current fair market value of the Ordinary Shares. The liability for unvested Ordinary Shares as of December 31, 2022 and 2021 amounts to €280 thousand and €458 thousand, respectively.

At the time of the Exchange, the 285,714 non-voting ordinary shares in NewAmsterdam Pharma underlying the Founder DRs were converted into 608,779 Ordinary Shares. The number of awards presented as comparative information for 2021 in the table below has been updated to reflect this conversion in 2022.

The movements in the number of Founder DRs outstanding are as follows:

	2022	2021
	Number of Ordinary Shares	Number of Ordinary Shares[(1)]
Outstanding as at January 1	**608,779**	**—**
Granted/purchased during the year	—	608,779
Outstanding as at December 31	**608,779**	**608,779**

(1) On November 22, 2022, the non-voting ordinary shares in NewAmsterdam Pharma outstanding of 285,714 were exchanged for 608,779 Ordinary Shares using an exchange ratio of approximately 2.13. The 2021 amounts and the opening balance as at January 1, 2022, have been re-stated to reflect this conversion.

As of December 31, 2022 and 2021, in total 367,804 and 215,609 Ordinary Shares underlying the Founder DRs had vested, respectively.

Note 21 — Loss per Share

Loss per share for the period presented has been determined by dividing the loss attributable to shareholders by the weighted average number of shares outstanding during the period. NewAmsterdam Pharma's former non-voting ordinary shares and voting ordinary shares are considered to be the same class of equity for purposes of determining the loss attributable per shareholder class per share.

As described in Note 4, Note 19 and Note 20, 17,016,872 NewAmsterdam Pharma shares were exchanged for 36,258,312 Ordinary Shares following the internal reorganization, which reflects the exchange ratio of approximately 2.13. Consequently, the weighted average number of Ordinary Shares outstanding for basic and diluted EPS for the prior periods have been restated as required by IFRS.

	December 31, 2021
Shares for basic EPS of NewAmsterdam Pharma	**11,325,442**
Exchange ratio	2.13
Adjusted number of shares	**24,131,427**

The following table sets forth the computation of original and restated basic and diluted loss per

share for the year ended December 31:

(In thousands of Euro, except share and per share amounts)	**2022**	**2021**
Loss for the year	**(78,052)**	**(28,599)**
Weighted average number of ordinary shares - original	81,559,780	11,325,442
Basic and diluted loss per share - original	**(0.96)**	**(2.53)**
Weighted average number of ordinary shares - restated	81,559,780	24,131,427
Basic and diluted loss per share - restated	**(0.96)**	**(1.19)**

At December 31, 2022, and 2021, outstanding share-based awards (see Note 20) was excluded from the calculation because their impact would be anti-dilutive. At December 31, 2022 and 2021, the total number of potential ordinary shares excluded amounted to 11,146,861 and 4,185,360, respectively.

Note 22 — Lease

The following table provides information about the Group's right of use assets at December 31:

	2022	**2021**
Opening balance at January 1	**162**	**—**
Additions	—	172
Depreciation	(64)	(10)
Impact of transaction of foreign currency	15	—
Total ROU asset at December 31	**113**	**162**

The following table provides information about the Group's lease liabilities at December 31:

	2022	**2021**
Opening balance at January 1	**164**	**—**
Additions	—	172
Repayment	(55)	(10)
Interest	9	2
Total lease liability at December 31	**118**	**164**
Current		
Lease liabilities	62	53
Non-current		
Lease liabilities	56	111

With effective date May 29, 2021, the Company leases office premises in Florida set to expire October 31, 2024. Refer to Note 13 for right of use lease asset details related to this finance lease liability.

Note 23 — Related Parties

The following table provides the total amount of transactions that have been entered into with

related parties for the relevant financial year ended December 31:

	Related party relationship	Type of transaction	Purchases from	Amounts owed to	Amounts owed by
2022					
FCPM III Services B.V. **("Forbion III")**	Common control	Rent and office services	40	12	—
2021					
FCPM III Services B.V. **("Forbion III")**	Common control	Rent and office services	20	21	—
Mr. M.H. Davidson	Exec. director & shareholder	Receivables	—	—	718

* Amounts receivable from this related party were with NewAmsterdam Pharma and comprised of outstanding principal and unpaid interest, with further details given in Note 14 which reflects the total loan receivable. Amount was fully settled in July 2022.

NewAmsterdam Pharma B.V. signed a services agreement with Forbion III where the Company could utilize office space and other facilities at the premises of Forbion III. The Services agreement is effective beginning March 2020 and continues for an indefinite period of time. As the lease grants each party the unilateral right to terminate the lease on giving 30 days' notice to the other party, for any reason and with no significant penalty, management concluded that the agreement did not contain a lease component and the full amount was expensed as Selling, General and Administration expenses during 2022 and 2021.

Terms and conditions of transactions with related parties

Transactions with related parties, other than the remuneration of certain non-executive directors as disclosed below, are made on terms equivalent to those that prevail in arm's length transactions. Outstanding balances at the year-end are unsecured and interest free and settlement generally occurs in cash. There have been no guarantees provided or received for any related party receivables or payables.

Compensation to Directors and Senior Managers of the Company

The Company's compensation includes base salary, as well as short and long-term incentive schemes.

Key Management Personnel ("**KMPs**") are those persons having authority and responsibility for planning, directing and controlling the activities of the Company, including the directors of the company. KMP include the Chief Executive Officer, Chief Financial Officer, Chief Scientific Officer, Chief Operating Officer, Chief Business Officer and Vice President of Research and Development. The following table sets forth the total compensation paid to KMPs during the period:

	2022	2021
Short-term employee benefits	2,741	1,505
Share-based payments	3,203	753
Total compensation paid to key management personnel	**5,944**	**2,258**

Additionally, certain non-executive directors of the Company who serve as representatives of the Company's shareholders and as such, have of received cash remuneration from the Company during the years ended December 31, 2022 and 2021 totaling €61 thousand and €26 thousand, respectively, and share-based payment expenses during the period totaling €62 thousand and €13 thousand, respectively. John Kastelein M.D., non-executive director at December 31, 2022 and executive director at December 31, 2021, received cash remuneration from the Company during the years ended December 31, 2022 and 2021 totaling €479 thousand and €787 thousand, respectively, and share-based payment expenses totaling €597 thousand and €347 thousand, respectively, exclusively for his role as Chief Scientific Officer of the Company.

The remaining non-executive directors receive remuneration directly from certain shareholders (Entities affiliated with Forbion, Frazier Lifesciences Sponsor LLC and affiliates, and Entities affiliated with Bain Capital Life Sciences Investors, LLC) that is not recharged to the Company. The amount of this remuneration is not known by the Company.

Remuneration of the Board of Directors

The emoluments as referred to in Section 2:383(1) of the Dutch Civil Code, charged in the financial period to the company can be detailed as follows.

*2022 Board of Directors' remuneration**

(In thousands of Euro)	Salary	Bonus	Management fee	Share-based compensation	Total remuneration 2022
Executive director					
Michael Davidson, M.D.	210	173	248	1,303	1,934
Non-executive directors					
John Kastelein, M.D.	63	137	279	597	1,076
Louis Lange, M.D., Ph.D.	61	-	-	62	123
James N. Topper, M.D., Ph.D.	-	-	-	-	-
Juliette Audet	-	-	-	-	-
Sander Slootweg	-	-	-	-	-
Nicholas Downing, M.D.	-	-	-	-	-
Total	**334**	**310**	**527**	**1,962**	**3,133**

* John W. Smither and Janneke van der Kamp were appointed as temporary non-executive directors on January 14, 2023 and April 1, 2023, respectively, to fulfill vacant positions within the Board until their proposed appointment by the General Meeting at the next annual General Meeting.

Michael Davidson, M.D. and John Kastelein, M.D. have received a bonus based on the realization of targets set by the Group, all of which were achieved in 2022.

2021 Board of Directors' remuneration

(In thousands of Euro)	Salary	Bonus	Management fee	Share-based compensation	Total remuneration 2021
Executive director					
Michael Davidson, M.D.	-	-	790	250	1,040

John Kastelein, M.D.	-	-	787	347	1,134
Non-executive directors					
Louis Lange, M.D., Ph.D.	26	-	-	13	39
Juliette Audet	-	-	-	-	-
Sander Slootweg	-	-	-	-	-
Jason Dinges	-	-	-	-	-
Guarav Gupta	-	-	-	-	-
Wouter Joustra	-	-	-	-	-
Hugo Beekman	-	-	-	-	-
Philip Scheltens	-	-	-	-	-
Whit Bernard	-	-	-	-	-
Total	**26**	**-**	**1,577**	**610**	**2,213**

Options held by the Board of Directors

	Number of share options held as at December 31, 2022	Number of share options held as at December 31, 2021*	Exercise price per share
Executive director			
Michael Davidson, M.D.[(1)]	989,267	989,267	€ 1.16
Michael Davidson, M.D.[(2)]	2,440,538	-	$ 10.00
Non-executive directors			
John Kastelein, M.D.[(1)]	1,171,902	1,171,902	€ 1.16
John Kastelein, M.D.[(2)]	971,726	-	$ 10.00
Louis Lange, M.D., Ph.D.[(1)]	85,229	85,229	€ 1.16
Louis Lange, M.D., Ph.D.[(2)]	94,835	-	$ 10.00

* On November 22, 2022, the share options in NewAmsterdam Pharma outstanding were exchanged for Ordinary Shares using an exchange ratio of approximately 2.13. The 2021 amounts and the opening balance as at January 1, 2022, have been re-stated to reflect this conversion.

Conditions of the share options held by Executive and Non-executive directors are as follows:

(1) The grant date is July 8, 2021 and the final exercise date is July 7, 2031. 25% of the aggregate number of options shall vest on the 12-month anniversary of the applicable vesting commencement date and 1/36th of the remaining aggregate number of options shall vest on each subsequent monthly anniversary of the applicable vesting commencement date, until either the option is fully vested or the optionholder's continuous service terminates.

(2) The grant date is November 22, 2022 and the final exercise date is November 21, 2032. 1/48th of the aggregate number of options shall vest on each subsequent monthly anniversary of the applicable vesting commencement date, until either the option is fully vested or the optionholder's continuous service terminates.

No vested options held by the Board of Directors were exercised during the years ended December 31, 2022 and 2021.

Note 24 — Segment Reporting

Operating segments are components of the Company that engage in business activities from which it may incur expenses, for which discrete financial information is available and whose operating results are evaluated regularly by the Company's Chief Operating Decision Maker ("**CODM**") to make decisions about resources to be allocated to the segment and assess its performance. The activities of the Group are considered to be one segment which is reflected in its organizational structure and internal

reporting and comprises the research, development and subsequent commercialization of innovative and proprietary compounds that have a potential therapeutic effect in cardiovascular disease. The Company does not distinguish in its internal reporting different segments, neither business nor geographical segments. The Chief Executive Officer is identified as the CODM and reviews the operating results regularly to make decisions about the resources and to assess overall performance of the Company. Prior to 2022, the Board was identified as the CODM. The change in CODM did not impact any identification of segments.

Total revenue recognized of €97.5 million from the Menarini License during the year ended December 31, 2022 is derived entirely from Italy.

The following table shows the breakdown of the Group's non-current assets (i.e., intangible assets, property, plant and equipment and long-term prepaid expenses) by geographical location as of December 31:

	2022	2021
Non-current assets		
Netherlands	83,172	12
USA	278	178
Total	**83,450**	**190**

Note 25 — Supplemental Cash Flow Information

The following table shows supplemental cash flow information for the year ended December 31:

	2022	2021
Non-cash financing and investing activities		
IPR&D asset recognized resulting from equity issued to Amgen & MTPC shareholders	83,160	—
Derivative earnout obligation assumed on closing	6,633	—
Conversion of convertible debt to equity	—	11,667
Equity issued to FLAC shareholders in excess of proceeds received	56,913	—

Note 26 — Independent Auditor's Fee

The following fees were charged by Deloitte Accountants B.V. to the Company and its subsidiaries, as referred to in Section 2:382a(1) and (2) of the Dutch Civil Code. The costs are allocated to the year which the services are related to.

(In thousands of Euro)	Deloitte Accountants B.V. 2022	Deloitte Accountants B.V. 2021
Audit of financial statements	248	70
Other assurance services	1,677	-
Tax services	-	-
Other non-audit services	-	-
Total	**1,925**	**70**

Note 27 — Events After the Reporting Period

The Company evaluated subsequent events for recognition or disclosure through May 22, 2023, the date these consolidated financial statements were authorized for issuance by the Board.

On January 1, 2023, the Company granted options to purchase an aggregate of 4,171,572 Ordinary Shares to certain employees and directors. Such options each have an expiration date of ten years from the date of grant and an exercise price of $10.90.

On January 14, 2023, the Company granted options to purchase an aggregate of 18,600 Ordinary Shares to a non-executive director. Such options each have an expiration date of ten years from the date of grant and an exercise price of $10.22.

In January 2023, the Group achieved a clinical success milestone related to our Phase 2b ROSE2 clinical trial and as a result received a milestone payment from Menarini in April 2023 amounting to €5 million.

The Company announced on March 3, 2023 that David Topper, Chief Financial Officer, who provided advice and guidance in support of the Company's now complete public company transition, has resigned. The Company has appointed current Chief Accounting Officer, Louise Kooij, as Interim Chief Financial Officer. The Company intends to conduct a search for a new permanent chief financial officer.

4.2 Company Financial Statements

Statement of financial position

December 31, 2022
(before appropriation of the result)

	Note	As at December 31, 2022
(In thousands of Euro)		
Assets		
Fixed assets		
Financial fixed assets	1	496,462
Total fixed assets		**496,462**
Current assets		
Prepayments	2	1,676
Total current assets		**1,676**
Short-term liabilities		
Trade and other payables	3	2,676
Financial liabilities	4	3,888
Total short-term liabilities		**6,564**
Balance of current assets less short-term liabilities		**(4,888)**
Total assets less short-term liabilities		**491,574**
Long-term liabilities		
Financial liabilities	4	7,053
Total long-term liabilities		**7,053**
Equity	5	
Paid-in and called-up capital		9,787
Share premium		589,404
Other reserves		4,691
Accumulated loss		(27,576)
Loss for the period		(91,785)
Total equity		**484,521**
Total long-term liabilities plus equity		**491,574**

The accompanying notes are an integral part of these financial statements.

Company statement of profit or loss

(In thousands of Euro)	Note	Period ended December 31, 2022
Share in result of subsidiaries	1	(7,918)
Other income and expenses after taxes	6	(83,867)
Loss for the period after tax		**(91,785)**

The accompanying notes are an integral part of these financial statements.

Notes to the Company financial statements

General

Entity Information

NewAmsterdam Pharma Company N.V. (the "Company") is a global biotech company focused on the research and development of transformative therapies for cardio-metabolic diseases. The Company was incorporated in the Netherlands as a Dutch private company with limited liability (*Besloten Vennootschap met beperkte aansprakelijkheid*) under the name NewAmsterdam Pharma Company B.V. on June 10, 2022. On November 21, 2022, the Company's corporate form was converted to a Dutch public limited liability company (*Naamloze Vennootschap*) and its name was changed to NewAmsterdam Pharma Company N.V. The Group's principal place of business and registered office is Gooimeer 2-35, 1411 DC Naarden, The Netherlands. The company is registered at the Chamber of Commerce under number 864035792.

On November 21, 2021, the Company conducted an internal reorganization via obtaining all of the shares of NewAmsterdam Pharma Holding B.V. ("NewAmsterdam Pharma") by issuing 36,258,312 Company shares, with a par value of €0.12 in exchange of 17,016,872 NewAmsterdam Pharma shares of €0.01 par value to its shareholders. Immediately after giving effect to the exchange, a subsidiary of the Company merged with and into Frazier Lifesciences Acquisition Corporation ("FLAC"), with FLAC surviving as a wholly owned subsidiary of the Company. Upon consummation of the internal reorganization with NewAmsterdam Pharma, the merger of FLAC surviving as the wholly owned subsidiary of the Company, and an additional raise of equity financing through a private placement of Company shares ("PIPE Financing"), the Company was publicly listed on the Nasdaq on November 22, 2022. Reference is made to Note 4 in the consolidated financial statements for detailed disclosures regarding the capital reorganization and FLAC merger.

General accounting principles

The accounting standards used to prepare the financial statements
The company financial statements have been prepared according to the provisions of Part 9 Book 2 of the Dutch Civil Code. The accounting policies used are the same as those used for the consolidated financial statements in accordance with the provisions of article 362.8 of Part 9 Book 2 of the Dutch Civil Code. Participations in consolidated entities are accounted for using the asset value method applying the same accounting policies as those used in the consolidated financial statements. Subsidiaries are recognized from the date on which control is transferred to the Company or its intermediate holding entities.

Investments in participating interests are presented as financial fixed assets in the statement of financial position using the net asset value. If the Company's share of losses of subsidiaries equals or exceeds its interest in the participating interest (including related receivables, which are deemed part of the net investment), the Company does not recognize any further losses, unless it has incurred legal or constructive obligations or made payments on behalf of the investment. In such case, the Company will recognize a provision. If the participating interest subsequently reports profits, the Company resumes recognizing its share of those profits only after its share of the profits equals the share of losses not recognized.

Management has not identified any material uncertainties that may cast a significant doubt about the Company's ability to continue in operation at least twelve months from the date when the company financial statements are authorized for issue. With reference made to Note 4 in the consolidated financial statements, the Company received proceeds of €69.8 million as a result of the Business Combination and €228.3 million as a result of the concurrent PIPE Financing. In this respect, the company financial statements have been prepared on a going concern basis.

Since NewAmsterdam Pharma Company N.V. statement of profit or loss for 2022 is recognized in the consolidated financial statements, it is sufficient in the Company's financial statements to present a condensed statement of profit or Ioss in accordance with section 402 of Book 2 of the Dutch Civil Code.

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 NewAmsterdam Pharma Company N.V. should be read in conjunction with the consolidated IFRS financial statements.

The financial statements are the first set of financial statements and have been prepared for a period of 6 months commencing on the date of incorporation up to December 31, 2022, the end of the calendar year in accordance with the company's articles of association.

1. Financial fixed assets

NewAmsterdam Pharma Company N.V. has direct interests in the subsidiaries listed in Note 4 (in the Notes to the consolidated financial statements).

Movements in the financial fixed assets is as follows:

(In thousands of Euro)	**Investment in consolidated subsidiaries**	**Intercompany receivables**	**Total**
Balance at June 10, 2022	**-**	**-**	**-**
Investments	142,613	-	142,613
Increase in intercompany receivables	-	361,767	361,767
Share in results of subsidiaries	(7,918)	-	(7,918)
Balance at December 31, 2022	**134,695**	**361,767**	**496,462**

The Company applies the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for intercompany receivables. To measure the expected credit losses, intercompany receivables have been grouped based on shared credit risk characteristics and the days past due. There is no provision for expected credit losses as at December 31, 2022 given that there have been no credit losses since inception. The Company's maximum exposure to credit risk for intercompany receivables is the carrying amount at the reporting date. Such risk is controlled by the Company due to its direct interests in subsidiaries serving as counterparties.

The investment in subsidiaries is carried at €496.5 million and does not include any provision for impairment on December 31, 2022.

Name	Principal place of business	Country of incorporation	Percent equity interest 2022
NewAmsterdam Pharma Holding B.V.	Naarden	The Netherlands	Directly 100%
Frazier Lifesciences Acquisition Corporation ("FLAC")	Delaware, USA	United States of America	Directly 100%
NewAmsterdam Pharma B.V.	Naarden	The Netherlands	Indirectly 100%
NewAmsterdam Pharma Corporation	Florida, USA	United States of America	Indirectly 100%

2. Prepayments

(In thousands of Euro)	As at December 31, 2022
Prepaid insurance	1,676
Total prepayments	**1,676**

3. Trade and other payables

(In thousands of Euro)	As at December 31, 2022
Accrued expenses	545
Accrued wages and bonuses	196
Share based payment liabilities	1,935
Total trade and other payables	**2,676**

Reference is made to Note 11 in the consolidated financial statements for further information on Trade and other payables.

4. Financial liabilities

(In thousands of Euro)	As at December 31, 2022
Derivative earnout liability	7,053
Total financial liabilities - non-current	**7,053**
Derivative warrant liabilities	3,888
Total financial liabilities - current	**3,888**

Reference is made to Note 17 in the consolidated financial statements for further information on financial liabilities and Note 16 in the consolidated financial statements for disclosure on related risks.

5. Equity

The Company was incorporated in the Netherlands as a Dutch private company with limited liability (*Besloten Vennootschap met beperkte aansprakelijkheid*) under the name NewAmsterdam Pharma Company B.V. on June 10, 2022. On November 21, 2022, the Company's corporate form was converted to a Dutch public limited liability company (N*aamloze Vennootschap*) and its name was changed to NewAmsterdam Pharma Company N.V.

Additionally on November 21, 2022, the shareholders of NewAmsterdam Pharma exchanged their interest for ordinary shares in the share capital of the Company, such that the Company became the direct parent of NewAmsterdam Pharma. This exchange is accounted for as a capital reorganization, with NewAmsterdam Pharma being the accounting predecessor. Accumulated loss of €20.9 million, as assumed by the Company, span from NewAmsterdam Pharma's inception until the date of the internal reorganization.

On December 31, 2022, the Company's authorized share capital amounted to €21 million divided into 175 million ordinary shares, each with a nominal value of €0.12. As at December 31, 2022, the total number of issued ordinary shares was 81,559,780. On December 31, 2022, the issued share capital totaled to €9.8 million. No dividend was distributed in 2022.

On November 22, 2022, the Company became public, by listing its ordinary shares on the Nasdaq. Reference is made to Note 17 and Note 19 in the consolidated financial statements for further information on the earnout obligation realized and on equity, respectively. The other reserves relate to the share-based payments reserve.

(In thousands of Euro)	**Paid-in and called-up capital**	**Share premium**	**Other reserves**	**Accumulated loss**	**Loss for the period, after tax**	**Total equity**
Balance at June 10, 2022	**-**	**-**	**-**	**-**	**-**	**-**
Issue of ordinary shares to NewAmsterdam Pharma shareholders	4,351	159,205	591	(20,943)	-	143,204
Issue of ordinary shares to FLAC shareholders	1,582	125,084	-	-	-	126,666
Issue of ordinary shares for PIPE Financing	2,815	225,528	-	-	-	228,343
Issue of ordinary shares to Amgen & MTPC shareholders	1,039	82,121	-	-	-	83,160
Transaction costs on issue of shares	-	(2,534)	-	-	-	(2,534)
Earnout obligation realized upon Closing	-	-	-	(6,633)	-	(6,633)
Share-based payments	-	-	4,100	-	-	4,100
Loss for the period, after tax	-	-	-	-	(91,785)	(91,785)
Balance at December 31, 2022	**9,787**	**589,404**	**4,691**	**(27,576)**	**(91,785)**	**484,521**

Appropriation of Result

During the period under review, no dividend was distributed out of the Company's accumulated loss. The managing directors propose to allocate the net profit for the period to the accumulated loss. The proposed appropriation of profit has not been reflected in the Company's balance sheet per December 31, 2022.

Difference in equity and profit/loss between the company and consolidated financial statements

There is no difference between equity according to the Company statement of financial position and equity according to the consolidated statement of financial position. The loss of €91.8 million according to the Company income statement reflects the Company's income and expenses since inception and the share in result of subsidiaries since the date of internal reorganization until the period ended December 31, 2022. The loss of €78.1 million according to the consolidated income statement reflects the results of the Group for the year ended December 31, 2022.

6. Other income and expenses after taxes

Other income and expenses after taxes include the following Company income and expenses:

(In thousands of Euro)	**Period ended December 31, 2022**
Management fee	152
Research and development expenses	(1,973)
General and administrative expenses	(6,904)
Share listing expense	(60,600)
Change in fair value - earnout and warrants	(976)
Net foreign exchange gains/(losses)	(13,566)
Total other income and expenses after taxes	**(83,867)**

7. Income Taxes

Fiscal Unity in the Netherlands
With an effective date of November 21, 2022, NewAmsterdam Pharma Company N.V. formed a fiscal unity with NewAmsterdam Pharma Holding B.V. and NewAmsterdam Pharma B.V. for corporate income tax purposes. A company and its subsidiaries that are part of the fiscal unity are jointly and severally liable for the tax payable by the fiscal unity.

Reference is made to Note 12 in the consolidated financial statements for further information on Income Taxes.

8. Employees and employee information

The Company employed 3 full-time employees in 2022, all of which were employed within the Netherlands.

Reference is made to Note 23 in the consolidated financial statements for further information on compensation paid to Key Management Personnel.

The Company is responsible for settling share-based payment transactions with employees of the Group, and these are recognized as equity-settled share-based payment transactions since they are settled in shares of the Company. Reference is made to Note 20 in the consolidated financial statements for disclosure on the share-based payments.

9. Remuneration of the Board of Directors

Reference is made to Note 23 in the consolidated financial statements for further information on remuneration of, and options held by, the Board of Directors.

10. 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 NewAmsterdam Pharma Company N.V. and close relatives are regarded as related parties. Other than the Key Management Personnel as stated in Note 23 in the consolidated financial statements and the investment in consolidated subsidiaries, intercompany receivables and related movements as stated in Note 1 in the company financial statements, there were no related party transactions.

11. Independent Auditor's fee

Reference is made to Note 26 in the consolidated financial statements.

12. Events after the reporting period

Reference is made to Note 27 in the consolidated financial statements.

Signature page to the NewAmsterdam Pharma Company N.V. 2022 financial statements

/s/ M.H. Davidson
M.H. Davidson

/s/ J.J.P. Kastelein
J.J.P. Kastelein

/s/ J.N. Topper
J.N. Topper

/s/ J.B. Audet
J.B. Audet

/s/ L. Lange
L. Lange

/s/ N.S. Downing
N.S. Downing

/s/ H.S. Slootweg
H.S. Slootweg

/s/ J.W. Smither
J.W. Smither

/s/ H.J. van der Kamp
H.J. van der Kamp

Other information

Statutory provisions

In accordance with Article 24.3 of the Articles of association, the result for the period is at the disposal of the Annual Meeting of Shareholders.

Independent auditor’s report

Refer to the report of the independent auditor on the next page.

5 CONTROLS AND PROCEDURES

5.1 Risk management and control systems

A. Disclosure Controls and Procedures

As required by Rule 13a-15 under the Exchange Act, management, including our Chief Executive Officer and our Interim Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Disclosure controls and procedures refer to controls and other procedures designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Disclosure controls and procedures include, without limitations, controls and procedures designed to ensure that information required to be disclosed by us in our reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding our required disclosures.

Based on the foregoing, our chief executive officer and our chief financial officer have concluded that, as of December 31, 2022, our disclosure controls and procedures were not effective due to the material weaknesses in our internal control over financial reporting across the principles for each component of the COSO framework at the entity level (i.e. control environment, risk assessment, monitoring, information & communication and control activities) and accordingly, across its business and IT processes. Specifically, the material weaknesses that were identified, individually or in the aggregate, included the following:

- a lack of consistent and documented risk assessment procedures and control activities related to financial reporting, among which a sufficient level of management review and approval, manual processes, roles and responsibilities, and adequate application and controls over information technology; and
- failure to maintain a sufficient complement of personnel commensurate with its accounting and reporting requirements as it continues to grow as a company, and ability to: (i) design and maintain formal accounting policies, procedures and controls over the fair presentation of financial statements; (ii) analyze, record and disclose complex accounting matters timely and accurately; and (iii) design and maintain controls over the preparation and review of journal entries and financial statements, including maintaining appropriate segregation of duties.

We have taken steps, and intend to continue taking steps, to develop a remediation plan designed to address these material weaknesses; however, our overall control environment is still immature and may expose us to errors, losses or fraud.

B. Changes in Internal Control Over Financial Reporting

In early 2023, we began to implement a comprehensive risk assessment process to identify and assess risks of material misstatement, upon which we intend to design and implement an effective control framework. Furthermore, the Company will continue to invest in additional qualified finance, accounting and IT resources to address the growth of the Company and further increase the effectiveness of our internal control environment.

5.2 In control statement

On the basis of reports and information provided to the Board and its committees, the Board is of the opinion that:

a. this report provides sufficient insight into any failings in the effectiveness of the Company's risk management and control systems;

b. the Company's risk management and control systems provide reasonable assurance that the Company's financial reporting does not contain material inaccuracies;

c. based on the Company's state of affairs as at the date of this report, it is justified that the Company's financial reporting is prepared on a going concern basis; and

d. this report states the material risks and uncertainties that the Company faces, to the extent they are relevant to the expectation of the Company's continuity for a period of twelve months after the date of this report.

The Board determined that due to the limited size and complexity of the Company, no internal audit department had to be established in 2022.

Furthermore, the Board confirms that:

a. to the best of its knowledge, the statutory annual accounts included in this report give a true and fair view of the assets, liabilities, financial position and profit or loss of the Company and its consolidated subsidiaries taken as a whole; and

b. this report includes a fair review concerning the position, on the balance sheet date, and the development and performance of the business of the Company and its consolidated subsidiaries taken as a whole, together with a description of the principal risks and uncertainties that they face.

6 CORPORATE GOVERNANCE

6.1 Dutch Corporate Governance Code

For the fiscal year to which this report relates, the Dutch Corporate Governance Code 2016 (the "**DCGC**") applied to the Company as of the completion of the Business Combination. The text of the DCGC can be accessed at http://www.mccg.nl. The DCGC has been updated in the course of 2022, with effect from January 1, 2023 and therefore the updated DCGC will only apply to us as from the fiscal year 2023.

Except as set out below, during the fiscal year to which this report relates, the Company complied with the principles and best practice provisions of the DCGC, to the extent that these are directed at the Board.

Some deviations may relate to the fact that the DCGC only applied to the Company for one month in the fiscal year to which this report relates.

Risk management (best practice provisions 1.2.2, 1.4.1)

See explanation in chapter 5.1 under A.

Internal audit function (best practice provisions 1.3.1, 1.3.2, 1.3.3, 1.3.4 and 1.3.5)

The Company has not established an internal audit department, considering its size of organization and given that the DCGC only applied to the Company for one month in the fiscal year to which this report relates. We have engaged an external party to support us with setting up and describing our internal control environment, implementing the required policies, followed by control operating effectiveness and remediation if required.

Independence (best practice provision 2.1.7, 2.1.8, 2.1.9, 2.3.4)

The composition of our Board and its committees currently is not compliant with the DCGC, as not more than half of the members the members of the Board and its committees are independent within the meaning of the DCGC. The Board considers that the experience and continuity of its members outweigh the disadvantages of these deviations from the DCGC. In addition, some members of the Board have specific in-depth institutional knowledge about the Company, its business and the environment in which the Company operates, which is very valuable to the Company. For the reasons provided, the Company currently does not fully comply with this best practice provision, but will continuously evaluate its ability to appoint new independent board members to the Board, which the Company has done recently by appointing two independent members as temporary members of the Board, subject to their proposed appointment at the 2023 General Meeting.

Evaluation (best practice provision 2.2.8, 2.4.6)

The Board intends to perform, at least once per year, a self-evaluation about the functioning of the Board as a whole. However, given the current organization of the Company and its recent transformation into a listed company, our Board has not performed any formal evaluations in the fiscal year to which this report relates.

Compensation (best practice provisions 3.1.2, 3.2.3, 3.3.2, 3.3.3 and 3.4.2)

The shareholders of the Company have adopted a policy regarding remuneration of the Board. A summary of the compensation earned by the directors and the executive officers of the Company for the financial year to which this report relates is consistent with the remuneration policy approved by the shareholders and is set forth in the Company's public filings with the SEC. Consistent with the Company's remuneration policy and market practice in the United States, the trading jurisdiction of our common shares, and in order to further support our ability to attract and retain the right highly qualified candidates for our Board:

- options awarded to our executive director as part of his compensation could (subject to

the terms of the option awards and option plan) vest and become exercisable during the first four years after the date of grant;

- our directors may generally sell our common shares held by them at any point in time, subject to applicable law, Company policy and applicable arrangements;

- our non-executive directors may be granted compensation in the form of shares, options and/or other equity-based compensation; and

- our executive director may be entitled to a payment in excess of his respective annual base salary in the event of severance.

Our executive director was appointed by resolution of the General Meeting on November 21, 2022 for a term through the 2025 General Meeting. Consistent with SEC applicable regulations, the executive director's agreement with the Company is not filed with the SEC. It is therefore also not posted to the Company's website. The executive director's compensation is consistent with the remuneration policy, with that of similarly-situated executives in peer companies, and set forth in several of the Company's public filings with the SEC.

Majority requirements for dismissal and overruling binding nominations (best practice provision 4.3.3)

Our directors are appointed by our General Meeting upon the binding nomination by our Board. Our General Meeting may only overrule the binding nomination by a resolution passed by a two-thirds majority of votes cast, provided such majority represents more than half of the Company's issued share capital. In addition, except if proposed by our Board, our directors may be suspended or dismissed by our General Meeting at any time by a resolution passed by a two-thirds majority of votes cast, provided such majority represents more than half of the Company's issued share capital. We believe that these provisions support the continuity of the Company and its business and that those provisions, therefore, are in the best interests of our shareholders and our other stakeholders.

6.2 Code of business conduct and ethics and other corporate governance practices

The Company has adopted a code of business conduct and ethics which can be accessed at https://ir.newamsterdampharma.com/corporate-governance/governance-overview . The Company does not voluntarily apply other formal codes of conduct or corporate governance practices.

6.3 Risk management and control systems

See chapter 5.1 of this report for an overview of the main characteristics of the Company's risk management and control systems relating to the process of financial reporting by the Company and the Company's group companies whose financial information is included in the Consolidated Financial Statements.

6.4 General Meeting

6.4.1 Functioning of the General Meeting

Annually, at least one general meeting of the Company (the "**General Meeting**") must be held. This annual General Meeting must be held within six months after the end of the Company's fiscal year. A General Meeting must also be held within three months after the Board has decided that it is likely that the Company's equity has decreased to or below 50% of its paid up and called up share capital. In addition, without prejudice to the best practice provisions of the DCGC with respect to invoking a 'response period' or the provisions under Dutch law with respect to invoking a 'cooling-off period', a General Meeting must be held when requested by one or more shareholders and/or others with meeting rights under Dutch law collectively representing at least 10% of the Company's issued share capital, provided that certain criteria are met. Any additional General Meeting shall be convened whenever the Board would so decide. Each General Meeting must be held in Arnhem, Assen, The Hague, Haarlem, 's-Hertogenbosch, Groningen, Leeuwarden, Lelystad, Maastricht, Middelburg, Rotterdam, Schiphol (Haarlemmermeer), Utrecht or Zwolle.

For purposes of determining who have voting rights and/or meeting rights under Dutch law at a General Meeting, the Board may set a record date. The record date, if set, shall be the 28th day prior to that of the General Meeting. Those who have voting rights and/or meeting rights under Dutch law on the record date and are recorded as such in one or more registers designated by the Board shall be considered to have those rights at the General Meeting, irrespective of any changes in the composition of the shareholder base between the record date and the date of the General Meeting. The Company's articles of association require shareholders and others with meeting rights under Dutch law to notify the Company of their identity and their intention to attend the General Meeting. This notice must be received by the Company ultimately on the seventh day prior to the General Meeting, unless indicated otherwise when such General Meeting is convened.

6.4.2 Powers of the General Meeting

All powers that do not vest in the Board pursuant to applicable law, the Company's articles of association or otherwise, vest in the Company's general meeting (the "**General Meeting**"). The main powers of the General Meeting include, subject in each case to the applicable provisions in the Company's articles of association:

a. the appointment, suspension and dismissal of Directors;

b. the approval of certain resolutions of the Board concerning a material change to the identity or the character of the Company or its business;

c. the reduction of the Company's issued share capital through a decrease of the nominal value, or cancellation, of ordinary shares in its capital;

d. the adoption of the Company's statutory annual accounts;

e. the appointment of the Dutch independent auditor to examine the Company's statutory

annual accounts;

f. amendments to the Company's articles of association;

g. approving a merger or demerger by the Company, without prejudice to the authority of the Board to resolve on certain types of mergers and demergers if certain requirements are met; and

h. the dissolution of the Company.

In addition, the General Meeting has the right, and the Board must provide, any information reasonably requested by the General Meeting, unless this would be contrary to an overriding interest of the Company.

6.4.3 Shareholder rights

Each ordinary share in the Company's capital carries one vote. Shareholders, irrespective of whether or not they have voting rights, have meeting rights under Dutch law (including the right to attend and address the General Meeting, subject to the concept of a record date as described in chapter 6.4.1). Furthermore, each ordinary share in the Company's capital carries an entitlement to dividends and other distributions as set forth in the Company's articles of association. Pursuant to the Company's articles of association, any such dividend or other distribution shall be payable on such date as determined by the Board and the Board may also set a record date for determining who are entitled to receive any such dividend or other distribution (irrespective of subsequent changes in the shareholder base). The record date for dividends and other distributions shall not be earlier than the date on which the dividend or other distribution is announced. In addition, shareholders have those rights awarded to them by applicable law.

6.5 Board

The Board is charged with managing the Company's affairs, which includes setting the Company's policies and strategy. Our executive director is charged primarily with the Company's day-to-day business and operations and the implementation of the Company's strategy. Our non-executive directors are charged primarily with the supervision of the performance of the duties of the Board. Each director is charged with all tasks and duties of the Board that are not delegated to one or more other specific directors by virtue of Dutch law, the Company's articles of association or any arrangement catered for therein (e.g., the internal rules of the Board). In performing their duties, our directors shall be guided by the interests of the Company and of the business connected with it.

As at December 31, 2022, the Board was composed as follows (which are all still directors on the Board as of the date of this report):

Name and age	Gender identity	Nationality	Date of initial appointment	Expiration of current term of office	Attendance rate at meetings of the board
Michael Davidson, M.D. (66)*	M	American	21-11-2022	2025	100%
John Kastelein, M.D. (69)**	M	Dutch	21-11-2022	2023	100%
James N. Topper, M.D., Ph.D. (61)**	M	American	21-11-2022	2025	100%
Juliette Audet (37)**	F	French	21-11-2022	2024	100%
Louis Lange, M.D., Ph.D. (74)**	M	American	21-11-2022	2024	100%
Sander Slootweg (54])**	M	Dutch	21-11-2022	2023	100%
Nicholas Downing, M.D. (38)**	M	American	21-11-2022	2023	100%

John W. Smither and Janneke van der Kamp were appointed as temporary non-executive directors on January 14, 2023 and April 1, 2023, respectively, to fulfill vacant positions within the Board until their proposed appointment by the General Meeting at the next annual General Meeting.

* Executive director
** Non-executive director

Executive Director

Dr. Michael Davidson. Michael Davidson, M.D., was appointed as our Chief Executive Officer and executive director in November 2022. Dr. Davidson served NewAmsterdam Pharma as its Chief Executive Officer and an executive director from August 2020 to November 2022. Prior to joining NewAmsterdam Pharma, Dr. Davidson was the founder and Chief Executive Officer of Corvidia Therapeutics, Inc. from January 2016 until April 2018 and the Chief Science/Medical Officer from April 2018 until July 2020, when Corvidia was acquired by Novo Nordisk A/S for up to $2.1 billion. Dr. Davidson, who is a leading expert in the field of lipidology and was named in The Best Doctors in America for the past 15 years, is also currently a professor of medicine and director of the lipid clinic at the University of Chicago. Dr. Davidson co-founded and served as the Chief Medical Officer of Omthera Pharmaceuticals, Inc. in 2008, which was later acquired by AstraZeneca Pharmaceuticals in 2013 for up to $443 million. His research background encompasses both pharmaceutical and nutritional clinical trials including extensive research on statins, novel lipid-lowering drugs, and omega-3 fatty acids. Dr. Davidson is board-certified in internal medicine, cardiology, and clinical lipidology and served as President of the National Lipid Association from 2010 to 2011. Dr. Davidson currently serves on the board of directors of Tenax Therapeutics, Inc. (Nasdaq: TENX) and Silence Therapeutics plc (Nasdaq: SLN). Dr. Davidson also serves on the boards of two private biotechnology companies, Sonothera and NanoPhoria Bioscience. Dr. Davidson received his B.A. and M.S. from Northwestern University and his M.D. from The Ohio State University School of Medicine.

We believe Dr. Davidson's extensive experience in the field of cardiology and his prior management experience provide him the qualifications and skills to serve on the Board.

Non-Executive Directors

Dr. John Kastelein. John Kastelein, M.D., Ph. D. FESC, was appointed as our Chief Scientific Officer and non-executive director in November 2022. Dr. Kastelein co-founded NewAmsterdam Pharma in 2020 served as its Chief Scientific Officer and an executive director from January 1, 2020 to November 2022. Dr. Kastelein has also served as the chief executive officer of Vascular Research Network Inc. ("VRN") since January 2013 and as the Chief Medical Officer of Staten Biotechnology B.V. since January 2018. Dr. Kastelein also serves as emeritus professor of medicine and was the chair of the department of vascular medicine at the Academic Medical Center of the University of Amsterdam. He serves on the advisory board of the Dutch Atherosclerosis Society. In 2011 he received the ZonMw Pearl for his research in the field of gene therapy. Dr. Kastelein also serves on the board of directors of North Sea Therapeutics Inc., VRN and Oxitope Pharma Inc. Dr. Kastelein also serves as an advisor to a number of biotech and pharmaceutical companies. Dr. Kastelein was awarded a doctorate in medicine (with honors) from the University of Amsterdam, trained in internal medicine at the Academic Medical Center of the University of Amsterdam, and trained in lipidology and molecular biology at the University of British Columbia in Vancouver. Dr. Kastelein published his first clinical research on CETP-inhibition in the New England Journal of Medicine in 1997.

We believe Dr. Kastelein's deep scientific and medical knowledge about NewAmsterdam Pharma's product candidate and his experience in senior management provide Dr. Kastelein with the qualifications and skills to serve on the Board.

Dr. James N. Topper. James N. Topper, M.D., Ph.D., was appointed to the Board in November 2022. Dr. Topper previously served as FLAC's Chief Executive Officer and Chairman of the FLAC Board from October 2020 until November 2022. Dr. Topper currently serves as a Managing Partner of Frazier Life Sciences ("Frazier"). He joined Frazier in 2003 and opened Frazier's Menlo Park office in the same year. Throughout his 15 years as a Managing Partner, Dr. Topper has invested across over 35 companies encompassing a broad spectrum of life science and biopharmaceutical companies. Dr. Topper has led and served as a board member for many of Frazier's successful life sciences investments, including Acerta Pharma BV (sold to AstraZeneca), Amunix Pharmaceuticals, Inc. (sold to Sanofi), Aptinyx Inc. (Nasdaq: APTX), Calistoga Pharmaceuticals, Inc. (co-founder, sold to Gilead Sciences), Entasis Therapeutics Holdings Inc. (sold to Innoviva), Frazier Lifesciences Acquisition Corporation, Mavupharma (sold to AbbVie), Rempex (sold to The Medicines Company), Incline (co-founder, sold to The Medicines Company), Alnara (sold to Lilly), Portola, Inc. (co-founder, Nasdaq: PTLA), Phathom Pharmaceuticals Inc. (Nasdaq: PHAT), CoTherix, Inc (sold to Actelion), and Threshold Pharmaceutical, Inc. (Nasdaq: THLD). He currently represents Frazier on the boards of Alpine Immune Sciences (Nasdaq: ALPN), AnaptysBio, Inc. (Nasdaq: ANAB), Lassen Therapeutics, Seraxis Holdings, Inc., Enlaza Therapeutics, Inc., Serum, Inc. and Sudo Biosciences, Inc. In 2011 and 2016, Dr. Topper was named to the Midas List of leading venture capitalists, and in 2013, Dr. Topper was recognized by Forbes as a top ten healthcare investor. Dr. Topper received his M.D. and Ph.D. in Biophysics from Stanford and his B.S. from the University of Michigan.

We believe that Dr. Topper's experience overseeing Frazier's investments in biotechnology, his experience in senior management positions and his significant knowledge of industry, medical and scientific matters, provide Dr. Topper with the qualifications and skills to serve on the Board.

Juliette Audet. Juliette Audet was appointed to the Board in November 2022. Ms. Audet previously served on the NewAmsterdam Pharma board from 2020 until November 2022. Ms. Audet has been a partner at Forbion Venture Capital since January 2021 and served as a principal at Forbion from October 2019 until December 2020. Prior to joining Forbion, Ms. Audet was a Principal at Novartis Venture Fund based in Cambridge, Massachusetts from January 2018 until July 2019. Ms. Audet currently serves on the board of directors of Mestag Therapeutics Limited. Ms. Audet received an M.B.A., with

distinction, from Harvard Business School and her M.Sc in physics from EPFL (Lausanne, Swiss Federal Institute of Technology).

We believe that Ms. Audet's extensive experience investing in life science companies and her managerial experience provider her the qualifications and skills to serve on the Board.

Dr. Louis Lange. Louis Lange, M.D., Ph.D., was appointed to the Board in November 2022. Dr. Lange previously served on the NewAmsterdam Pharma board from 2021 to November 2022. Dr. Lange previously served as the chief of cardiology and a professor of medicine at the Washington University School of Medicine and was one of the early academicians in molecular cardiology. Dr. Lange founded and served as the chief executive officer and chairman of CV Therapeutics, Inc. (Nasdaq: CVTX) from 1990 until 2019, and as a senior advisor to Gilead Sciences, Inc. from 2009 until 2019, following its acquisition of CV Therapeutics. Dr. Lange currently serves as a general partner with Asset Management Ventures. Dr. Lange also serves on the board of directors of Stealth Biotherapeutics Corp. (private), BioPlus Acquisition Corp. (Nasdaq:BIOS), Amygdala Neurosciences, Inc. and Recardia, Inc. Dr. Lange previously served on the board of directors of Audentes Therapeutics, Inc. (sold to Astellas Pharma Inc.) and Epiphany Tech Acquisition Corp., (Nasdaq: EPHY). Dr. Lange has a Bachelor's degree from the University of Rochester, an M.D. from Harvard University and a Ph.D. in Biological Chemistry, also from Harvard University.

We believe that Dr. Lange's board experience, medical background and experience as a public company officer, provide Dr. Lange with the qualifications and skills to serve on the Board.

Sander Slootweg. Sander Slootweg was appointed to the Board in November 2022. Mr. Slootweg previously served on the NewAmsterdam Pharma board from 2020 until November 2022. Mr. Slootweg co-founded Forbion and has served as managing partner since 2006. Mr. Slootweg currently serves on the boards of several of Forbion's portfolio companies including Replimune Group Inc., NorthSea Therapeutics B.V., Azafaros B.V., Xention, Oxyrane Belgium NV and Forbion European Acquisition Corporation (Nasdaq: FRBN). Mr. Slootweg was responsible for several substantial exits: Forbion's major position in Argenx SE (Nasdaq: ARGX), Dezima's acquisition by Amgen in 2015 for up to $1.55 billion and the sale of Biovex Group, Inc. to Amgen in 2011 for up to $1 billion. Mr. Slootweg has previously served on the boards of Pulmagen Therapeutics, Fovea Pharmaceuticals SA (sold to Sanofi-aventis in 2009), uniQure N.V. (IPO on Nasdaq in 2014), Argenta Limited (sold to Galapagos NV in 2010), Alantos Pharmaceuticals, Inc. (sold to Amgen in 2007), Impella CardioSystems AG (sold to Abiomed Inc. in 2005), Pieris Pharmaceuticals, Inc. (IPO on Nasdaq in 2015). Before co-founding Forbion, Mr. Slootweg was an investment director at ABN AMRO Capital Life Sciences. Mr. Slootweg holds degrees in business and financial economics from the Free University of Amsterdam and business administration from Nijenrode University, The Netherlands.

We believe that Mr. Slootweg's experience investing in and serving on multiple boards of life science companies, provide Mr. Slootweg with the qualifications and skills to serve on the Board.

Dr. Nicholas Downing. Nicholas Downing, M.D., was appointed to the Board in November 2022. Dr. Downing joined Bain Capital Life Sciences in 2018 where he currently serves as a Managing Director. Prior to joining Bain Capital, Dr. Downing was a resident physician at the Brigham and Women's Hospital in Boston from 2015 until 2018, where he cared for patients on the inpatient medical service and in the outpatient clinic. Throughout his medical career, Dr. Downing has been an active health policy researcher and is the author of over 40 articles in the peer-reviewed scientific literature. Prior to his medical career, Dr. Downing was a consultant at McKinsey and Company where he worked with clients in the pharmaceutical, hospital and financial services industries on a wide range of strategic problems. Dr. Downing also serves as a director on the board of Kestra Medical Technologies, Ltd., Cardurion Pharmaceuticals, Inc. and River Renal Companies. Dr. Downing graduated from Harvard College magna cum laude with a degree in chemistry. He received an M.D. cum laude from Yale University School of Medicine.

We believe that Dr. Downing's medical experience, as well as his experience investing and serving on the boards of life science companies provide Dr. Downing with the qualifications and skills to serve on the Board.

John W. Smither. John Smither was appointed as temporary non-executive director in January 2023 in fulfilment of a vacant position within the Board until his proposed appointment by the General Meeting at the next annual General Meeting. Mr. Smither previously served as the Chief Financial Officer of Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) from May 2019 until March 2021 and the Chief Financial Officer of Sienna Biopharmaceuticals, Inc. (Nasdaq: SNNA) from April 2018 until March 2019. Mr. Smither also served as the interim Chief Financial Officer at Kite Pharma (a Gilead Sciences, Inc. company) from October 2017 until April 2018 during its integration with Gilead. Mr. Smither currently serves on the board of directors and audit committee chair of eFFECTOR Therapeutics, Inc. (Nasdaq: EFTR) and Applied Molecular Transport, Inc. (Nasdaq: AMTI). Mr. Smither also serves as a member of the nomination and corporate governance committee and the compensation committee of eFFECTOR Therapeutics and Applied Molecular Transport, respectively. Mr. Smither previously served on the board of directors of Achaogen, Inc. and Principia Biopharma Inc. Mr. Smither also has 15 years' experience as a practicing CPA (inactive), including time spent as an audit partner with Ernst & Young LLP.

We believe that Mr. Smither's experience as the Chief Financial Officer for a number of public companies and his experience serving on the board of directors and audit committees of other public life science companies provide Mr. Smither with the qualifications and skills to serve on the Board.

Janneke van der Kamp. Janneke van der Kamp was appointed a temporary non-executive director as of April 1, 2023 in fulfilment of a vacant position within the Board until her proposed appointment by the General Meeting at the next annual General Meeting. Ms. van der Kamp currently serves as the Chief Commercial Officer of Grünenthal and previously spent two decades in roles of increasing responsibility at Novartis, ultimately serving on the Pharma Executive Committee as Global Head of Product & Portfolio Strategy and then Head of Pharma Region Europe from January 2017 until January 2022. While at Novartis, Ms. van der Kamp supported the launch of Novartis' key cardiovascular disease medicines, as well as the company's efforts in immunology, dermatology, neuroscience, ophthalmology, and respiratory disease. Ms. van der Kamp received her M.S. in chemistry from Utrecht University and M.B.A. from INSEAD.

We believe that Ms. van der Kamp's operational experience in the pharmaceutical industry and business development experience provide Ms. van der Kamp that qualifications and skills to serve on the Board.

All of our non-executive directors, except for Juliette Audet, Sander Slootweg, Dr. John Kastelein, Dr. James N. Topper, and Dr. Nicholas Downing, are independent within the meaning of the DCGC.

6.6 Committees

6.6.1 General

The Board has established an audit committee, a compensation committee and a nomination and corporate governance committee. Each committee operates pursuant to its charter.

As at December 31, 2022, the commitees were composed as follows:

Name	Audit committee	Compensation committee	Nomination and corporate governance committee
Juliette Audet	X*		
Louis Lange, M.D., Ph.D.	X	X*	X
Sander Slootweg	X		X*
Nicholas Downing, M.D.		X	X

* Chairperson

No attendance rate is included in above table, as the committees were only established as of November 21, 2022. Therefore, no committee meetings have been held in the fiscal year to which this report relates.

6.6.2 Audit committee

The responsibilities of our audit committee include:

a. monitoring the Board with respect to (i) the relations with, and the compliance with recommendations and follow-up of comments made by, the Company's internal audit function and the Dutch independent auditor, (ii) the Company's funding, (iii) the application of information and communication technology by the Company, including risks relating to cybersecurity and (iv) the Company's tax policy;

b. issuing recommendations concerning the appointment and the dismissal of the head of the Company's internal audit function;

c. reviewing and discussing the performance of the Company's internal audit function;

d. reviewing and discussing the Company's audit plan with the Company's internal audit function and the Dutch independent auditor;

e. reviewing and discussing the essence of the audit results with the Company's internal audit function:

f. reviewing and discussing certain matters with the Dutch independent auditor:

g. determining whether and, if so, how the Dutch independent auditor should be involved in the content and publication of financial reports other than the Company's financial statements;

h. reviewing and discussing the effectiveness of the design and operation of the Company's risk management and control systems;

i. advising the Board regarding the nomination of the Dutch independent auditor for (re)appointment or dismissal and preparing the selection of the Dutch independent auditor for such purpose, as relevant; and

j. submitting proposals to the Board concerning the engagement of the Dutch independent auditor to audit the Company's financial statements, including the scope of the audit, the materiality to be applied and the auditor's compensation.

During the fiscal year to which this report relates, our audit committee met once. This is because the audit committee was only established as of November 21, 2022.

6.6.3 Compensation committee

The responsibilities of our compensation committee include:

a. submitting proposals to the Board concerning changes, as relevant, to the Company's compensation policy (the "**Compensation Policy**");

b. submitting proposals to the Board concerning the compensation of individual Directors; and

c. preparing the disclosure included in this report on the Company's compensation practices.

During the fiscal year to which this report relates, our compensation committee met once. This is because the compensation committee was only established as of November 21, 2022.

6.6.4 Nomination and corporate governance committee

The responsibilities of our nomination and corporate governance committee include:

a. drawing up selection criteria and appointment procedures for our directors;

b. reviewing the size and composition of the Board and submitting proposals for the composition profile of the Board;

c. reviewing the functioning of individual directors and reporting on such review to the Board;

d. drawing up a plan for the succession of our directors;

e. submitting proposals for (re)appointment of our directors; and

f. supervising the policy of the Board regarding the selection criteria and appointment procedures for the Company's senior management.

During the fiscal year to which this report relates, our nomination and corporate governance committee did not meet. This is because the nomination and corporate governance committee was only established as of November 21, 2022.

6.7 Evaluation

As the entire Board was only in function for a month during the fiscal year to which this report relates, the Board has not formally evaluated its own functioning, the functioning of the committees of the Board and that of the individual directors. The Board recognises the importance of evaluation and is committed to peform evaluations of its own functioning, the functioning of the committees of the Board and that of the individual directors on a yearly basis.

6.8 Diversity

The Company has a diversity policy with respect to the composition of the Board. The Company is committed to supporting, valuing and leveraging the value of diversity. However, the importance of diversity, in and of itself, should not set aside the overriding principle that someone should be recommended, nominated and appointed for being "the right person for the job". Although the Company has not set specific targets with respect to particular elements of diversity, the Company believes that it is important for the Board to represent a diverse composite mix of personal backgrounds, experiences, qualifications, knowledge, abilities and viewpoints. The Company seeks to combine the skills and experience of long-standing members of the Board with the fresh perspectives, insights, skills and experiences of new members. To further increase the range of viewpoints, perspectives, talents and experience within the Board, the Company strives for a mix of ages in the composition of those bodies, but also does not set a specific target in this respect. The Company recognises and welcomes the value of diversity with respect to age, gender, race, ethnicity, nationality, sexual orientation and other important cultural differences. The Company is committed to seeking broad diversity in the composition of the Board and will consider these attributes when evaluating new candidates in the best interests of the Company and its stakeholders. In terms of experience and expertise, the Company intends for the Board to be composed of individuals who are knowledgeable in one or more specific areas detailed in the Company's diversity policy.

The Company believes that the composition of the Board is such, that the Company's diversity objectives, as outlined above, have been achieved.

6.9 Corporate values and code of business conduct and ethics

We have a code of business conduct and ethics which covers a broad range of matters including the handling of conflicts of interest, compliance issues and other corporate policies such as insider trading and equal opportunity and non-discrimination standards. We believe our code of business conduct and ethics is effective. The code of ethics is available for all employees and is additionally published on the Company's website (www.newamsterdampharma.com).

The adoption of our code of ethics applies to all directors, officers and employees of NewAmsterdam Pharma N.V. and its subsidiaries and encompasses our culture and main corporate values, being honesty, accountability, integrity, professionalism and fairness. Our commitment to the highest level of ethical conduct should be reflected in all of the Company's business activities, including, but not limited to, relationships with employees, customers, suppliers, competitors, regulatory agencies, the public and our shareholders. All of our employees, officers and directors must conduct themselves according to the language and spirit of the code of ethics and seek to avoid even the appearance of improper behavior. The Company strives for a culture of the "tone from the top" that will contribute to the development and sustainability of long-term value creation throughout the enterprise. The board of directors measures the extent to which the code is complied with by the number of reports that are made in relation to the code of ethics. In the financial year to which this board report relates, no reports were made in relation to the code of ethics.

7 COMPENSATION

7.1 Compensation policy

Pursuant to Section 2:135(1) DCC, the General Meeting has adopted a Compensation Policy. The Compensation Policy is designed to contribute to the Company's strategy, long-term interests and sustainability by:

a. attracting, retaining and motivating highly skilled individuals with the qualities, capabilities, profile and experience needed to support and promote the growth and sustainable success of the Company and its business;

b. driving strong business performance, promoting accountability and incentivising the achievement of short and long-term performance targets with the objective of furthering long-term value creation in a manner consistent with the Company's identity, mission and values;

c. assuring that the interests of the Directors are closely aligned to those of the Company, its business and its stakeholders; and

d. ensuring overall market competitiveness of the Compensation Packages, while providing the Board sufficient flexibility to tailor the Company's compensation

practices on a case-by-case basis, depending on the market conditions from time to time.

We believe that this approach and philosophy benefits the realisation of the Company's long-term objectives while keeping with the Company's risk profile.

7.2 Compensation of directors

See Note 23 (*Related Parties*) to the Consolidated Financial Statements included in chapter 4.1 for an overview of the implementation of the Compensation Policy in the fiscal year to which this report relates. In determining the level and structure of the compensation of the directors in the fiscal year to which this report relates relevant scenario analyses carried out in advance have been considered.

7.3 Pay ratio

The DCGC recommends that the Company provide a ratio comparing the total annual compensation of our executive director and that of a "representative reference group" determined by the Company. We have chosen to compare the cash compensation of our Chief Executive Officer to that of a median full-time permanent employee. Our methodology for producing this ratio excludes employees employed on a non-permanent or part-time basis. We have used the aggregate cash compensation over the fiscal year concerned as a reference amount (i.e., excluding the value of equity incentive awards and other non-cash compensation components). To calculate the ratio, we have annualized the salaries of employees who had worked with us for less than a year as at December 31, 2022. Based on this methodology, the ratio between the cash compensation of our Chief Executive Officer and a median full-time permanent employee for the fiscal year to which this report relates is 1 to 1.90 (rounded to the nearest integer).

8 RELATED PARTY TRANSACTIONS

For information on related party transactions, see Note 23 (*Related Parties*) to the Consolidated Financial Statements.

Where applicable, best practice provisions 2.7.3, 2.7.4 and 2.7.5 of the DCGC have been observed with respect to the transactions referenced above in this chapter 8.

9 PROTECTIVE MEASURES

We have adopted several provisions that may have the effect of making a takeover of our Company more difficult or less attractive, including:

- a provision that our directors may only be removed at the general meeting by a two-thirds majority of votes cast representing more than half of our issued share capital if such removal is not proposed by our Board;
- our directors being appointed on the basis of a binding nomination by our Board, which can only be overruled by the general meeting by a resolution adopted by at least a two-thirds majority of the votes cast, provided such majority represents more than half of the issued share capital (in which case the Board shall make a new nomination);

- a provision which allows the former chairman of our Board or our former chief executive officer to be charged with our management if all of our directors are absent or incapacitated; and
- 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.

In addition, Dutch law allows for staggered multi-year terms of our directors, as a result of which only part of our directors may be subject to appointment or re-appointment in any one year.

Furthermore, in accordance with the DCGC, shareholders who have the right to put an item on the agenda for our General Meeting or to request the convening of a General Meeting shall not exercise such rights until after they have consulted our Board. If exercising such rights may result in a change in our strategy (for example, through the dismissal of directors), our Board must be given the opportunity to invoke a reasonable period of up to 180 days to respond to the shareholders' intentions. If invoked, our Board must use such response period for further deliberation and constructive consultation, in any event with the shareholder(s) concerned and exploring alternatives. At the end of the response time, our Board shall report on this consultation and the exploration of alternatives to our General Meeting. The response period may be invoked only once for any given General Meeting and shall not apply (i) in respect of a matter for which a response period has been previously invoked or (ii) if a shareholder holds at least 75% of our issued share capital as a consequence of a successful public bid.

In addition, a statutory cooling-off period of up to 250 days was introduced, during which, if invoked by the Board, our General Meeting would not be able to dismiss, suspend or appoint directors (or amend the provisions in our articles of association dealing with such matters) unless those matters would be proposed by our Board. This cooling-off period could be invoked by our Board, in case (i) shareholders, using either their shareholder proposal right or their right to request a general meeting, propose an agenda item for the General Meeting to dismiss, suspend or appoint a director (or an amendment to our articles of association dealing with such matters) or (ii) a public offer for our Company is made or announced without our support, provided, in each case, that our Board believes that such proposal or offer materially conflicts with the interests of our Company and its business. In addition to the termination grounds provided under this bill, shareholders representing at least 3% of our issued share capital may request the Enterprise Chamber of the Amsterdam Court of Appeal (the "Enterprise Chamber") for early termination of the cooling-off period. The Enterprise Chamber must rule in favor of the request if the shareholders can demonstrate that (i) our Board, in light of the circumstances at hand when the cooling-off period was invoked, could not reasonably have come to the conclusion that the relevant shareholder proposal or hostile public offer constituted a material conflict with the interests of our Company and its business, (ii) our Board cannot reasonably believe that a continuation of the cooling-off period would contribute to careful policy-making or (iii) other defensive measures have been activated for our company during the cooling-off period which have not been terminated or suspended at the relevant shareholders' request within a reasonable period following the request (i.e., no 'stacking' of defensive measures). During a cooling-off period, if invoked, our Board must gather all relevant information necessary for a careful decision-making process. In this context, our Board must at least consult with shareholders representing at least 3% of our issued share capital at the time the cooling-off period was invoked and with the Dutch works council (in case such works council is esthablised). Formal statements expressed by these stakeholders during such consultations must be published on the Company's website to the extent these stakeholders have approved that publication. Ultimately one week following the last day of the cooling-off period, our Board must

publish a report in respect of its policy and conduct of affairs during the cooling-off period on our website. This report must remain available for inspection by shareholders and others with meeting rights under Dutch law at our office and must be tabled for discussion at the next General Meeting.

10 OTHER INFORMATION

10.1 Independent auditor's report

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INDEPENDENT AUDITOR'S REPORT

To the shareholders and Board of Directors of NewAmsterdam Pharma Company N.V.

Report on the audit of the financial statements for the period ended December 31, 2022

Our opinion

We have audited the financial statements for the period ended December 31, 2022 of NewAmsterdam Pharma Company N.V., based in Naarden, the Netherlands. The financial statements comprise the consolidated financial statements and the company-only financial statements.

In our opinion:

- The accompanying consolidated financial statements give a true and fair view of the financial position of NewAmsterdam Pharma Company N.V. as at December 31, 2022, and of its result and its cash flows for for the period ended December 31, 2022 in accordance with International Financial Reporting Standards as adopted by the European Union (EU-IFRS) and with Part 9 of Book 2 of the Dutch Civil Code.

- The accompanying company-only financial statements give a true and fair view of the financial position of NewAmsterdam Pharma Company N.V. as at December 31, 2022, and of its result for for the period ended December 31, 2022 in accordance with Part 9 of Book 2 of the Dutch Civil Code.

The consolidated financial statements comprise:

1. The consolidated statement of financial position as at December 31, 2022.

2. The following statements for the year ended December 31, 2022: the consolidated statements of profit or loss and comprehensive loss, consolidated statements of changes in equity and consolidated statements of cash flows.

3. The notes comprising a summary of the significant accounting policies and other explanatory information.

The company-only financial statements comprise:

1. The company-only statement of financial position as at December 31, 2022.

2. The company-only statement of profit or loss for the period ended December 31, 2022.

3. The notes comprising a summary of the significant accounting policies and other explanatory information.

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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 NewAmsterdam Pharma Company N.V. 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.

Report on the other information included in the consolidated annual accounts

In addition to the financial statements and our auditor's report thereon, the consolidated annual accounts contain other information.

The other information consists of:

- Management's Report, including, amongst others, the Remuneration Report and Compensation Statement, and Non-Financial Information.
- Other Information as required by Part 9 of Book 2 of the Dutch Civil Code.

Based on the following procedures performed, we conclude that the other information:

- Is consistent with the financial statements and does not contain material misstatements.
- Contains 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 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.

Deloitte.

Description of responsibilities regarding the financial statements

Responsibilities of the shareholders and 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.

Our responsibilities for the audit of the financial statements

Our objective is to plan and perform the audit assignment in a manner that allows us to obtain sufficient and appropriate audit evidence for our opinion.

Our audit has been performed with a high, but not absolute, level of assurance, which means we may not detect all material errors and fraud during our audit.

Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements. The materiality affects the nature, timing and extent of our audit procedures and the evaluation of the effect of identified misstatements on our opinion.

We have exercised professional judgement and have maintained professional scepticism throughout the audit, in accordance with Dutch Standards on Auditing, ethical requirements and independence requirements. Our audit included among others:

- Identifying and assessing the risks of material misstatement of the financial statements, whether due to fraud or error, designing and performing audit procedures responsive to those risks, and obtaining audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

- Obtaining an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.

- Evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.

- Concluding on the appropriateness of management's use of the going concern basis of accounting, and based on the audit evidence obtained, whether a material uncertainty exists related to events or

conditions that may cast significant doubt on the company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the company to cease to continue as a going concern.

- Evaluating the overall presentation, structure and content of the financial statements, including the disclosures.

- Evaluating whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

We communicate with management 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.

Rotterdam, May 22, 2023

Deloitte Accountants B.V.

Was signed
P.J. Seegers

10.2 Profit appropriation provisions

Pursuant to the Company's articles of association, any profits shown in the adopted statutory annual accounts of the Company shall be appropriated as follows, and in the following order of priority:

a. the Board shall determine which part of the profits shall be added to the Company's reserves; and

b. subject to a proposal by the Board to that effect, the remaining profits shall be at the disposal of the General Meeting for distribution on the ordinary shares.

10.3 Branches

The Company has no branch offices.

10.4 Shares carrying limited economic entitlement

There are currently no outstanding shares which carry a limited entitlement to the profits or reserves in the Company.

10.5 Cross reference table for annual reporting requirements

The following list of cross references identifies the location of each required item disclosed in this Annual Report:

Management Board Report

Source of requirement	Sub-section	Topic	Location	
RJ 400.1 - Notices applicable to all medium-sized and large legal entities	1011 - 1014	Business Policy	Section 2.1 Section 2.2	History and development of the Company Overview & strategy
	1021	Objective	Section 2.2	Overview & strategy
	1031	Corporate Structure	Section 2.2 Section 2.3	Overview & strategy Organizational structure
	1041-1042	Financial Developments	Section 2.5 Section 3	Operating results Risks associated with our business
	1051-1058	Risk Management	Section 3	Risks associated with our business
	1061	Culture and Behavior	Section 2.2	Overview & Strategy
	1071	Risk Policy for Financial Instruments	Section 4	Consolidated financial statements
	1081-1082	Code of Conduct	Section 6.2	Code of business conduct and ethics and other corporate governance practices
	1091-1095	Research and Development	Section 2.2 Section 2.5	Overview & strategy Operating results
	1101-1106	Future Prospects	Section 2.2 Section 2.5	Overview & strategy Operating results

	1111	Other Subjects	Section 2.2 Section 5	Overview & strategy Controls and procedures
RJ 400.4 Additional requirements based on listed shares or other securities	4033	Form of corporate governance statement	Section 6	Corporate Governance
	4044	Notices on corporate governance under the corporate governance code	Section 6	Corporate Governance

Annual Financial Statements

Source of requirement	**Sub-section**	**Topic**	**Location**	
RJ 430		Key figures	Section 2.5	Operating results
Article 2:392 DCC/RJ 410	410.101	Other information	Section 10	Other information
	410.102a	Other information	Section 10.1	Independent auditor's report
	410.102b	Other information	Section 6.4.3 Section 10.2	Profit appropriation provisions
	410.102e	Other information	Section 10.4	Shares carrying limited economic entitlement
	410.102f	Other information	Section 10.3	Branches

RJ = Guidelines on Annual Reporting (Richtlijnen voor de Jaarverslaggeving)

Signature page to the Dutch statutory board report of NewAmsterdam Pharma Company N.V. for the fiscal year ended December 31, 2022

/s/ M.H. Davidson
_____
M.H. Davidson

/s/ J.J.P. Kastelein
_____
J.J.P. Kastelein

/s/ J.N. Topper
_____
J.N. Topper

/s/ J.B. Audet
_____
J.B. Audet

/s/ L. Lange
_____
L. Lange

/s/ N.S. Downing
_____
N.S. Downing

/s/ H.S. Slootweg
_____
H.S. Slootweg

/s/ J.W. Smither
_____
J.W. Smither

/s/ H.J. van der Kamp
_____
H.J. van der Kamp