

**NewAmsterdam Pharma Company N.V.**

**Annual Report  
for the fiscal year ended December 31, 2024**

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# 1 INTRODUCTION

## 1.1 Preparation

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 to 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 (trading symbol: NAMS).

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, 2024 and, unless explicitly stated otherwise, information presented in this report is as at December 31, 2024.

## 1.2 Forward-looking statements

This report contains forward-looking statements. Forward-looking statements provide the Company's 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 in this report may include, for example, statements about:

- the potential liquidity and trading of the Company's public securities;
- the Company's ability to raise additional capital in sufficient amounts and/or on terms acceptable to it;
- the efficacy and safety of the Company's product candidate, obicetrapib, as well as reimbursement and anticipated market size and market opportunity;
- the Company's dependence on the success of its product candidate, obicetrapib, including obtaining of regulatory approval to market obicetrapib;
- the timing, progress and results of clinical trials for obicetrapib, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work and the period during which results of the trials will become available and marketing submissions made;
- the Company's ability to attract and retain senior management and key scientific personnel;
- the Company's limited experience in marketing or distributing products;
- managing the risks related to the Company's international operations;
- the Company's ability to achieve the broad degree of physician adoption and use and market

- acceptance necessary for commercial success;
- the Company's estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- developments regarding the Company's competitors and our industry;
- the impact of government laws and regulations;
- the Company's reliance on third parties for all aspects of the manufacturing of obicetrapib for clinical trials; and
- the Company's efforts to obtain, protect or enforce its patents and other intellectual property rights related to the Company's product candidate.

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. Actual results could differ materially from those anticipated in forward-looking statements for many reasons, including the factors described in the section titled "*3 Risks Associated with our Business*" in this Annual Report. Accordingly, you should not rely on these forward-looking statements, which speak only as of the date of this Annual Report. The Company undertakes no obligation to publicly revise any forward-looking statement to reflect circumstances or events after the date of this Annual Report or to reflect the occurrence of unanticipated events. You should, however, review the factors and risks that the Company describes in the reports it will file from time to time with the U.S. Securities and Exchange Commission (the "SEC").

In addition, statements that "we believe" and similar statements reflect the Company's beliefs and opinions on the relevant subject. These statements are based on information available to the Company as of the date of this Annual Report. While the Company believes that information provides a reasonable basis for these statements, that information may be limited or incomplete. The Company's statements should not be read to indicate that it has 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 the Company believes the expectations reflected in the forward-looking statements were reasonable at the time made, it cannot guarantee future results, level of activity, performance or achievements. You should carefully consider the cautionary statements contained or referred to in this section in connection with the forward-looking statements contained in this Annual Report and any subsequent written or oral forward-looking statements that may be issued by the Company or persons acting on its behalf.

Unless otherwise stated or the context otherwise indicates, (i) references to "we," "our," "us" or the "Company" refer to NewAmsterdam Pharma Company N.V., together with its subsidiaries and (ii) references to "NewAmsterdam Pharma" refer solely to NewAmsterdam Pharma Holding B.V., a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) incorporated under the laws of the Netherlands and its subsidiaries.

## 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 a business combination pursuant to the Business Combination Agreement, dated as of July 25, 2022 (the "Business Combination Agreement"), by and among the Company, Frazier Lifesciences Acquisition Corporation, a Cayman Islands exempted 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, nominal value €0.12 per share (the "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*);
- 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 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.

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 NewAmsterdam Pharma Options 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 1,743,135 Earnout Shares and 143,002 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.

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.

Our website address is [www.newamsterdampharma.com](http://www.newamsterdampharma.com). Our website and information included in or linked to our website are not part of this Annual Report. We file reports with the SEC, which we make available on our website free of charge. These reports include annual reports quarterly reports and amendments to such reports, each of which is provided on our website as soon as reasonably practicable after we electronically file such materials with or furnish them to the SEC. Our website also includes our Annual Report and information filed while we were a foreign private issuer. In addition, the SEC maintains a website ([www.sec.gov](http://www.sec.gov)) that contains reports, proxy and information statements and other information regarding issuers, like us, that file electronically with the SEC.

## 2.2 Overview and strategy

### Overview

We are a late-stage biopharmaceutical company whose mission is to improve patient care in populations with cardiometabolic diseases where currently approved therapies have not been adequate or well tolerated. We seek to fill a significant unmet need for a safe, well tolerated and convenient low-density lipoprotein cholesterol (“LDL-C”) lowering therapy. In multiple Phase 3 trials, we have investigated obicetrapib, an oral, low-dose, once-daily, highly selective cholesterol ester transfer protein (“CETP”) inhibitor, alone or as a fixed-dose combination with ezetimibe, as preferred LDL-C lowering

therapies to be used as an adjunct to statin therapy for patients at risk of cardiovascular disease (“CVD”) with elevated LDL-C, for whom existing therapies are not sufficiently effective or well tolerated. 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.

Obicetrapib is a next-generation, oral, low-dose, highly selective CETP inhibitor that we are developing to potentially overcome the limitations of current LDL-C lowering treatments. In addition to LDL-C, obicetrapib has shown significant reductions in lipoprotein(a) (“Lp(a)”) and small LDL particles, all with safety comparable to placebo. We believe that obicetrapib has the potential to be a once-daily oral CETP inhibitor for lowering LDL-C, if approved. In each of our Phase 3 clinical trials, BROADWAY and BROOKLYN, evaluating obicetrapib as an adjunct to high-intensity statin therapy, obicetrapib met its primary and secondary endpoints, with statistically significant reductions in LDL-C observed. In our Phase 3 TANDEM clinical trial, evaluating obicetrapib in combination with ezetimibe as an adjunct to high-intensity statin therapy, obicetrapib in combination with ezetimibe met its primary and secondary endpoints, with statistically significant reductions in LDL-C observed. In five of our Phase 2 clinical trials, TULIP, ROSE, OCEAN, ROSE2 and our Japan Phase 2b clinical trial, evaluating obicetrapib as a monotherapy or a combination therapy with ezetimibe 10 mg, we observed statistically significant LDL-C lowering with side effects similar in frequency and severity to placebo including muscle-related side effects and drug-related treatment-emergent serious adverse events (“TESAEs”). We have observed obicetrapib to be well tolerated in an aggregate of over 3,500 patients with low or moderately elevated LDL-C levels (“dyslipidemia”) in our clinical trials to date. Furthermore, we believe that obicetrapib’s oral delivery, demonstrated activity at low doses, chemical properties and tolerability make it well-suited for combination approaches.

Lowering of LDL-C, has been associated with major adverse cardiovascular events (“MACE”) benefit in trials of LDL-C lowering drugs, including the REVEAL trial with the CETP inhibitor, anacetrapib. In our Phase 3 BROADWAY clinical trial, we observed a 21% reduction in the exploratory MACE endpoint (coronary heart disease death, non-fatal myocardial infarction, non-fatal stroke and coronary revascularization) and we are performing a Phase 3 cardiovascular outcomes trial (“CVOT”), PREVAIL, to reconfirm this relationship.

Obicetrapib has shown to not only reduce LDL-C but also several additional biomarkers associated with MACE. To date, obicetrapib has shown reductions in non-HDL-C, apolipoprotein B (“ApoB”), and small dense lipoprotein particles (“sdLDL-P”). In our clinical trials, we have also observed reductions in Lp(a), which is believed to be an independent MACE risk factor, along with reductions in total lipoprotein (“LDL”) particles and more specifically small LDL particles, which are believed to be more atherogenic particles.

CVD is a leading cause of death worldwide. Atherosclerotic cardiovascular disease (“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 statin therapy alone. We estimate that in the United States there are approximately 30 million patients that are not at their risk-based LDL-C goals despite treatment with lipid lowering therapy, including approximately 13 million with ASCVD. Existing non-statin treatment options have been largely unable to address the needs of patients with high cholesterol due to limited efficacy, an

inconvenient injectable administration route and, in the past, market access restrictions. It is estimated that over 75% of ASCVD and heterozygous familial hypercholesterolemia (“HeFH”) outpatients prefer oral drugs to injectable therapies.

Our goal is to develop and commercialize an LDL-C lowering monotherapy and a fixed-dose combination therapy, which offers the advantage of a single, low dose, once-daily oral pill, and fulfills the significant unmet need for an effective and convenient LDL-C lowering therapy. If we obtain marketing approval, we intend to commercialize obicetrapib for patients with ASCVD and/or HeFH and elevated levels of LDL-C despite being treated with currently available optimal lipid lowering therapy.

We have partnered with Menarini, providing 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 (the “EU”), including in Japan and China. In addition to our partnership with Menarini, we may in the future utilize a variety of types of collaboration, license, monetization, distribution and other arrangements with other third parties relating to the development or commercialization, once approved, of obicetrapib or future product candidates or indications. We are also continually evaluating the potential acquisition or license of new product candidates.

The following table summarizes our current clinical programs:



\* Other than as noted, the pipeline represents trials that are currently ongoing. Projections are subject to inherent limitations. Actual results may differ from expectations. The timing of regulatory submissions is subject to additional discussions with regulators.

We conducted two Phase 3 pivotal clinical trials, BROADWAY and BROOKLYN, to evaluate obicetrapib as a monotherapy used as an adjunct to maximally tolerated lipid-lowering therapies to potentially enhance LDL-C lowering in patients with ASCVD and or HeFH. We announced topline results for BROOKLYN in July 2024 and for BROADWAY in December 2024, both of which met the primary endpoint for the study with safety and tolerability comparable to placebo. Over 2,500 patients were randomized in the BROADWAY trial and over 350 patients were randomized in the BROOKLYN trial. We currently expect to report additional data from each study over the course of 2025. In March 2022, we commenced our Phase 3 PREVAIL CVOT, 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 in at least 9,000 patients. We completed enrollment in PREVAIL in April 2024 and expect to complete the study by the end of 2026.

We are also investigating obicetrapib as a fixed-dose combination with ezetimibe, an oral cholesterol absorption inhibitor and LDL-C lowering therapy, and plan to seek approval for this fixed-dose combination in parallel with obicetrapib monotherapy. In our Phase 3 TANDEM trial, we evaluated the efficacy and safety of 10 mg obicetrapib and 10 mg ezetimibe as a fixed-dose combination used as an adjunct to diet and maximally tolerated lipid-lowering therapies to potentially enhance LDL-lowering in patients with HeFH, ASCVD or ASCVD risk equivalents. In November 2024, we reported data from the Phase 3 TANDEM trial, which met its primary and secondary endpoints, with safety and tolerability comparable to placebo.

Our goal is to submit a New Drug Application (“NDA”) for the fixed-dose combination shortly after submitting an NDA for obicetrapib as a monotherapy. We expect that efficacy and safety data from BROADWAY and BROOKLYN will be described in the fixed-dose combination product label, if approved.

We plan to seek approval of obicetrapib in the United States, the EU, Japan, China and the United Kingdom. We conducted multiple Phase 3 trials simultaneously, with clinical plans that incorporate feedback from the FDA, the EMA, the Japan Pharmaceuticals and Medical Devices Agency (“PMDA”) and the China National Medical Products Administration (“NMPA”).

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%; when combined with the gene for the amyloid precursor protein, hypothesized to be a driver of Alzheimer’s disease, the risk of developing disease analogous to Alzheimer’s disease was observed to greatly increase in the double transgenic mice. In a preclinical study, we observed that CETP inhibition promoted cholesterol removal from the brain and improved cognition. We commenced a Phase 2a open-label and single-arm trial in early 2022 in patients with early Alzheimer’s disease and the apolipoprotein E4 (“ApoE4”) naturally occurring variant to evaluate the pharmacodynamic and pharmacokinetic effects, safety and tolerability of obicetrapib. A total of 13 patients were given 10 mg obicetrapib and followed for 24 weeks. In September 2023, we announced initial data from this trial. We observed reductions in the levels of 24-hydroxycholesterol and 27-hydroxycholesterol of 11% and 12%, respectively, in the cerebrospinal fluid (“CSF”) compared to baseline. In addition, an increase of 8% compared to baseline in the Aβ42/40 ratio in patients’ plasma was observed and pTau181 levels were observed to be stable. Overall, obicetrapib was observed to be well-tolerated. No serious adverse events (“AEs”) were reported, nor were any AEs considered to be related to the trial drug.

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 statin therapy. We are planning preclinical studies to examine the potential of obicetrapib for patients suffering from diabetes and have included new onset of type 2 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. In the Phase 3 BROADWAY trial, we observed a statistically significant improvement in these prespecified AEs of special interest after one year of treatment that we hope to reconfirm in the PREVAIL CVOT trial.

## **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 board of directors (the "Board of Directors"), 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 the Board of Directors, 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. Ian Somaiya, our Chief Financial Officer, has nearly three decades of experience in senior leadership roles in the biopharmaceutical industry. Mr. Somaiya, our Chief Financial Officer, most recently served as CFO and Chief Business Officer of Elucida Oncology and, before that, as CFO of TCR<sup>2</sup> Therapeutics, where he guided the company through its initial public offering and two subsequent follow-on offerings, as well as led the company's finance, reporting, business development and investor relations functions. Prior to joining TCR<sup>2</sup> Therapeutics, Mr. Somaiya was a managing director and head of biotechnology research at BMO Capital Markets. He also served as a Managing Director and equity analyst at Nomura Securities, Piper Jaffray and Thomas Weisel Partners. BJ Jones, our Chief Commercial Officer, has three decades of commercial and launch experience in both large pharmaceutical and small biotech companies. Most recently, he served as CCO, Migraine & Common Diseases at Biohaven Pharmaceuticals, and led the commercial enterprise that launched Biohaven's Nurtec® ODT. Earlier in his career, Mr. Jones held leadership roles of increasing responsibility at Takeda Pharmaceuticals, AstraZeneca, Bristol-Myers Squibb, Boehringer Ingelheim and NitroMed, during which time he supported mass market product launches for notable brands including Excedrin Migraine®, Farxiga®, Pradaxa®, BiDil®, and Abilify®.

In addition, we are backed by leading life sciences investors, including Frazier Life Sciences, Bain Capital, Forbion, RA Capital and Viking Global. 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 securities in prior offerings at a significant discount to the market price.

## **Cardiovascular Disease and Hyperlipidemia**

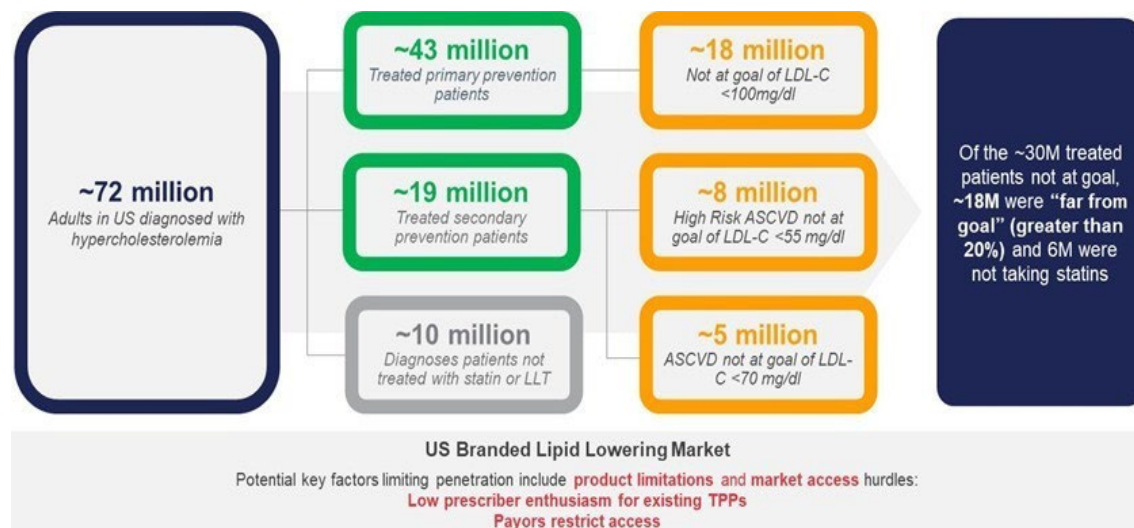
### ***Market Overview and Unmet Medical Need***

According to the World Health Organization, CVD is a leading cause of death globally and was responsible for approximately 19 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. Despite the availability of lipid lowering therapies, CVD events are on the rise. This increase despite aggressive secondary prevention efforts speaks to the concept known as "residual cardiovascular risk," defined as the risk of CVD events that persists despite treatment for, or achievement of targets for risk factors such as LDL-C.

LDL-C is the primary cause of ASCVD, and the target of many interventions aimed at reducing risk of cardiovascular events. An LDL-centric approach to risk reduction, namely with lipid lowering therapies, including statins, serves as the foundation for reducing residual cardiovascular risk. Data from a number of cardiovascular outcomes trials suggests that LDL-C is one of the most modifiable risk factors of ASCVD. Currently available strategies for LDL-C-lowering include lifestyle interventions and drug therapies including oral statins, ezetimibe, bempedoic acid, and injectable PCSK9 inhibitor therapies.

Lowering LDL-C has been observed to reduce morbidity and mortality in those with, or at risk of, CVD. The Cholesterol Treatment Trialists Collaboration (“CTT”) showed that lowering of LDL cholesterol by about 40 mg/dL with standard statin regimens safely reduced the 5-year incidence of major coronary events, revascularizations, and ischemic strokes by 22% . They also noted that a more pronounced absolute reduction of LDL-C may lead to substantially greater relative reduction in cardiovascular events. Furthermore, as seen in the Heart Protection Study and the CTT collaboration, benefit was seen in each tertile of baseline LDL-C. Similar relationships have also been documented in non-statin CVOTs for ezetimibe, two PCSK9 inhibitors, evolocumab and alirocumab, and the 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 availability of current lipid lowering therapies, many patients are unable to achieve their risk-based LDL-C goals. In the United States, we estimate that approximately 30 million patients remain above their risk-based LDL-C goal despite treatment with lipid lowering therapy, including approximately 13 million with ASCVD. Additionally, we estimate that approximately 10 million patients diagnosed with hypercholesterolemia are receiving no therapy at all.



Patients unable to achieve treatment goals with maximally tolerated statin therapy require additional lipid-lowering therapy. Cholesterol absorption inhibitors, ezetimibe, bempedoic acid or PCSK9 inhibitors are all prescribed as alternatives or adjuncts to statins. However, there are several limitations with these lines of therapy, such as limited efficacy, route of administration, market access hurdles and side effects. Because PCSK9 inhibitors are injectable, they pose a less attractive option for patients who broadly prefer oral medications, and they have not received the expected utilization by clinicians or patients. The two non-statin oral LDL-C-lowering therapies, ezetimibe and bempedoic acid, often do not provide the efficacy required for many patients, including high-risk ASCVD patients, that have more aggressive LDL-C goals, and bempedoic acid has label warnings of hyperuricemia and

tendon rupture. Therefore, there remains a significant unmet medical need for therapies to reduce LDL-C levels and residual cardiovascular risk in a convenient dosage form, and with a more favorable tolerability and safety profile to encourage long-term use and patient compliance. We believe that a potent, convenient, safe and well-tolerated low-dose oral medication to reduce LDL-C could fulfill this unmet need.

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

We believe that 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, highly selective CETP inhibitor with powerful LDL-C lowering capability. We are developing obicetrapib as both a monotherapy and a fixed-dose 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 and substantially reduced lipophilicity, that we believe give it more favorable properties as a drug candidate compared to prior CETP inhibitors. We have observed a favorable tolerability profile for obicetrapib in an aggregate of over 3,500 patients with dyslipidemia from Phase 1 through Phase 3 clinical trials. We conducted two Phase 3 pivotal trials, FCROSS and BROOKLYN, to evaluate obicetrapib as a monotherapy used as an adjunct to maximally tolerated lipid-lowering therapies to potentially enhance LDL-C lowering in patients with ASCVD and/or HeFH. We completed enrollment for BROADWAY in July 2023 and for BROOKLYN in April 2023. Over 2,500 patients were randomized in the BROADWAY trial and over 350 patients were randomized in the BROOKLYN trial. We reported top-line data from BROOKLYN in July 2024 and from BROADWAY in December 2024, and currently expect to report additional data from each study over the course of 2025. In March 2022, we commenced our Phase 3 PREVAIL CVOT, 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 completed enrollment in PREVAIL in April 2024 and expect to complete the trial by the end of 2026.

We also continue investigating obicetrapib as a fixed-dose combination with ezetimibe following the announcement of data from our Phase 3 TANDEM trial. In parallel with the ROSE2 trial, we formulated two prototype fixed-dose combination tablets of obicetrapib and ezetimibe. These formulations were compared to the co-administration of obicetrapib and ezetimibe in a pilot bioequivalence trial, which was completed in the first half of 2023. Based on the results of this pilot bioequivalence trial and the data and learnings from our ROSE2 trial, we selected a formulation for a fixed-dose combination tablet of obicetrapib and ezetimibe and initiated TANDEM, a Phase 3 pivotal trial, to evaluate 10 mg obicetrapib and 10 mg ezetimibe as a fixed-dose combination used as an adjunct to diet and maximally tolerated lipid-lowering therapies to potentially enhance LDL-C lowering in patients with HeFH, ASCVD or ASCVD risk equivalents, in the first quarter of 2024 and announced topline data in November 2024.

We believe that obicetrapib has the potential to significantly impact the existing treatment paradigm for patients with ASCVD and/or HeFH and elevated levels of LDL-C, and that the key differentiating attributes of our product candidate include the following:

- ***Enhanced LDL-C reduction capability.*** We believe that obicetrapib's physical, pharmacokinetic and biopharmaceutical properties position it to potentially demonstrate more favorable potency and enhanced LDL-C lowering capability than previous CETP inhibitors. In

previously conducted clinical trials in patients with moderately high LDL-C levels with or without prior statin therapy, obicetrapib has been observed to lower LDL-C both as a monotherapy and a combination therapy with ezetimibe (an approved LDL-C-lowering medication). In our Phase 3 BROADWAY and BROOKLYN clinical trials, we observed a mean LDL-C reduction capability of 33% and 36%, respectively, compared to placebo in patients treated with 10 mg obicetrapib on top of high-intensity statins. In our Phase 3 TANDEM clinical trial, we observed a mean LDL-C reduction of 52% in patients treated with a combination of 10 mg obicetrapib and 10 mg of ezetimibe as an adjunct to high-intensity statins, when compared to placebo.

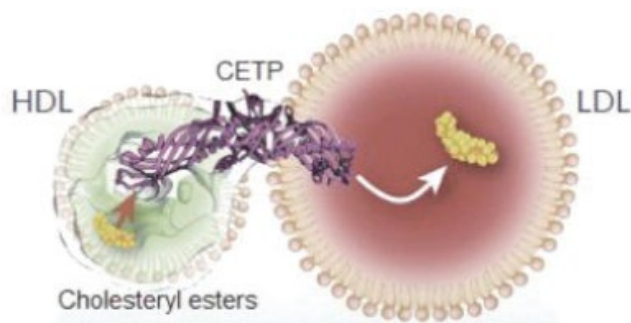
- **Promising tolerability profile.** Patients are often non-compliant with existing cholesterol-lowering therapies, particularly statin therapy, due to their side effect profiles, which could result in suboptimal treatment outcomes and disease progression. In three of our Phase 3 and five of our Phase 2 clinical trials of obicetrapib, we observed statistically significant LDL-lowering activity combined with a similar incidence of generally moderate side effects compared to placebo and no drug-related, treatment-emergent serious AEs. In addition, CETP inhibitors previously under development were observed to produce anti-diabetic benefits in Phase 3 CVOTs, which was also shown in obicetrapib, and 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, an oral small molecule, is better suited for combination with other oral treatments as oral fixed-dose combination products.
- **Patient access.** In addition, payor confidence is essential to ensuring access for patients. Based on the LDL-lowering activity of obicetrapib and oral route of administration, we believe payors will perceive the LDL-C 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-C lowering therapies, i.e., statins and PCSK9 inhibitors, CETP inhibition enhances the removal of ApoB, a protein found in lipoprotein particles that contributes to atherosclerosis. However, unlike statins, based on observations from our Phase 2 and Phase 3 clinical trials, obicetrapib also decreases the presence of 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 (“a package” of cholesterol contained within a particle that contains ApoB) has the tendency to penetrate the inner lining of the arterial wall becoming trapped 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 result in ulceration of the vessel wall which causes acute clotting of the blood and a heart attack or a stroke. Another lipoprotein particle, Lp(a), functions in the circulation as a “sink” for oxidized phospholipids and is also prone, like ApoB, to becoming 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 one of the most prominent risk factors for the development of CVD.

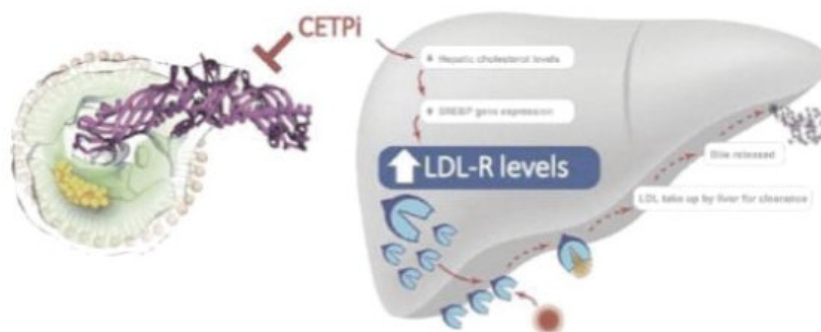
LDL-C and ApoB levels are mainly regulated by the liver through a surface protein known as the LDL receptor. Most current LDL-C lowering therapies work, at least in part, by increasing the number of LDL receptors, and thereby increasing the clearance of LDL particles from the blood. Statin therapy is the current standard of care for patients with ASCVD or HeFH and elevated levels of LDL-C. Statin

therapy reduces 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; in addition, statins upregulate the LDL receptor, resulting in lower blood cholesterol. PCSK9 inhibitors, another LDL-C-lowering treatment, also increase the presence of LDL receptors by inhibiting PCSK9, an enzyme involved in the degradation of LDL receptors. Two other LDL-C 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. CETP can also attach to an LDL particle and form a bridge to transfer cholesterol from HDL to LDL, as shown in the figure below. Consequently, CETP inhibitors, including obicetrapib, reduce the cholesterol concentration of LDL particles and increase the cholesterol concentration of HDL particles. This results in a decrease of the cholesterol pool in the liver as a result of the augmented excretion of cholesterol via the liver into the bile and ultimately the feces. The liver also produces more LDL receptors thereby resulting in more LDL-C particles and ApoB being cleared from the bloodstream. In animal models, CETP inhibition has been shown to block the transfer of cholesterol from HDL particles to LDL particles 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 particles and the formation of larger HDL particles. Consequently, we have observed an increase in the excretion of cholesterol via the liver into digestive tract and an upregulation of LDL receptors on the liver, resulting in an enhanced clearances of LDL or ApoB-containing lipoproteins from the body. In addition, there is evidence that CETP inhibition also promotes cholesterol excretion into the intestines directly contributing to the reduced cholesterol levels in the liver thus maintaining upregulation of LDL receptors.



sdLDL-P are also believed to be an important predictor of CVD risk, with lower levels of sdLDL-P having been observed to correlate closely to lower cardiovascular risk. The measurement of using LDL particle (“LDL-P”) size and particles numbers is an alternative approach to determining CVD risk assessment and research suggest that LDL-P size, density and numbers may be more closely correlated to CVD risk than LDL-C. Increased levels of LDL-P suggest an increased presence of sdLDL-P which may have a greater potential to develop into arterial plaque due to their increased time in circulation compared to larger LDL-P and greater ability to become trapped in the arterial wall. Research has suggested that treatments lowering LDL-C alone may trigger a disconnect between LDL-C and LDL-P, which, given the observed strong connection between LDL-P and CVD risk, suggests there is a need for a drug which lowers both.

### Limitations of Current Non-Statin Therapies

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

However, the needs of patients at very high risk to experience a future cardiovascular event with elevated levels of LDL-C despite being treated with maximally tolerated statin therapy remain largely unaddressed by current non-statin treatment options, which have only modest efficacy 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.** The non-statin cholesterol absorption inhibitor ezetimibe functions 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 as monotherapy or when given in combination with statin therapy has been observed to reduce LDL-C by approximately 13% to 20%. Despite its modest efficacy, ezetimibe is the most prescribed non-statin lipid lowering therapy with approximately 11% market share.
- **Nexletol/Nexlizet.** The other currently available oral non-statin therapy, Nexletol/Nexlizet, which inhibits the enzyme ATP citrate lyase, an enzyme involved in cholesterol synthesis, shows only relatively modest improvement in lowering LDL-C. 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 it, thus limiting its access and slowing uptake.
- **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 and HeFH 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 particles, thereby reducing LDL-C levels in the body. We believe that obicetrapib can improve upon existing therapies by providing a combination of potent LDL-C lowering activity favorable tolerability and the ability to be administered orally.

Other CETP inhibitors have reached varying stages of clinical development, but none have been approved or otherwise able to generate a potent, safe and well-tolerated low-dose oral option. We believe that the prior CETP inhibitor programs did not select optimal compounds because they focused on exploring the prominent increase in HDL-C rather than the potential for lowering LDL-C. Given the focus on HDL-C raising, we believe their clinical trial designs were suboptimal. Nevertheless, anacetrapib, the latest of the prior CETP inhibitors, provided clinical support for the proposition 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, one CETP inhibitor, torcetrapib, experienced off-target toxicity resulting in increased blood pressure and elevated aldosterone concentration in Phase 2 clinical trials. While another CETP inhibitor, dalcetrapib, did not experience the off-target toxicity as observed with torcetrapib, the drug had no LDL-C lowering activity and therefore no effect on reducing major adverse cardiovascular outcomes.

Given the emphasis on the HDL-C raising capabilities of the prior CETP inhibitors in development, the associated CETP inhibitor programs also used CVOTs designed to evaluate patients with controlled rather than elevated LDL-C levels. Therefore, we believe these study designs minimized the potential to observe relative reductions in CVD risk. In addition, we believe the evacetrapib CVOT was too short (a median duration of only two years) and most likely the sample size too low for the full magnitude of MACE benefits to be observed based on the modest reduction in LDL-C achieved. Similar CVOTs with other agents that lowered LDL-C by a similar magnitude required at least three years to demonstrate a MACE benefit, including the CVOTs of the CETP inhibitor anacetrapib.

In the Phase 3 REVEAL CVOT investigating the efficacy of anacetrapib in approximately 30,000 patients with ASCVD receiving intensive atorvastatin therapy, there was an observed correlation between MACE benefits for anacetrapib and the magnitude of the LDL-C reduction, suggesting that CETP inhibitors work according to the same principle as statin therapy 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 9% 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 10 mg for our Phase 3 development program given its observed LDL-C-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 ASCVD or HeFH patients with elevated LDL-C levels despite being treated with currently available optimal lipid lowering therapy. Obicetrapib has intrinsic properties, such as ionizable features and substantially reduced lipophilicity, that we believe give it more favorable physical, pharmacokinetic and biopharmaceutical properties as a drug candidate compared to other CETP inhibitors.

### **Clinical Development Plan**

We conducted 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 2 ROSE2 trial, we evaluated 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. In parallel with the ROSE2 trial, we formulated two prototype fixed-dose combination tablets of obicetrapib and ezetimibe. These formulations were compared to the co-administration of obicetrapib and ezetimibe in a pilot bioequivalence trial, which was completed in the first half of 2023. Based on the results of this pilot bioequivalence trial and the data and learnings from our ROSE2 trial, we selected a formulation for a fixed-dose combination tablet of obicetrapib and ezetimibe. We initiated TANDEM, a Phase 3 pivotal trial, to evaluate 10 mg obicetrapib and 10 mg ezetimibe as a fixed-dose combination used as an adjunct to diet and maximally tolerated lipid-lowering therapies to potentially enhance LDL-lowering in patients with HeFH, ASCVD or ASCVD risk equivalents, in the first quarter of 2024 and released topline data in November 2024.

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 for the 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 announced initial data from this trial in September 2023.

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

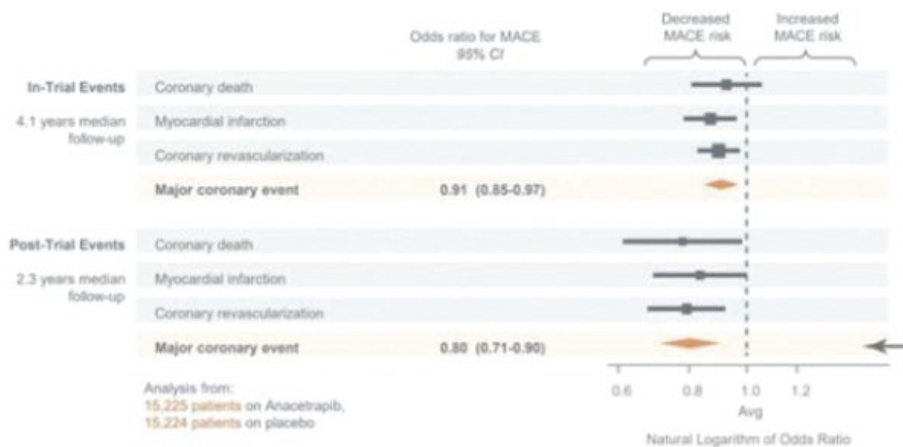


\*Other than as noted, the pipeline represents trials that are currently ongoing. Projections are subject to inherent limitations. Actual results may differ from expectations. The timing of regulatory submissions is subject to additional discussions with regulators.

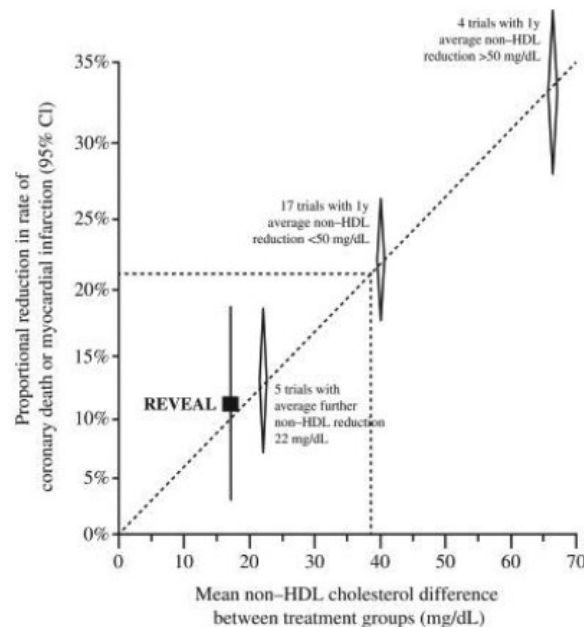
### Obicetrapib for Cardiovascular Disease

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-C 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 trial 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 for the hypothesis 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 trial of anacetrapib is consistent with the findings of the 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 non-HDL of 17 mg/dL, as seen in REVEAL, would correspond to the 11% reduction in coronary death and myocardial infarction observed in REVEAL.



\*The graphic above presents a linear prediction of MACE benefit, as discussed above. Actual results may differ materially.

With these learnings in mind, we are executing a phase 3 clinical development plan for obicetrapib focused on patients with elevated baseline LDL-C and that is designed to support a broad CVD label, if successful. To date, we have completed seven Phase 1 trials, five Phase 2 trials and three Phase 3 trials of obicetrapib, and we are currently conducting a Phase 3 PREVAIL CVOT trial.

### ***Planned and Ongoing Clinical Trials for Cardiovascular Disease***

### *Phase 3 PREVAIL Cardiovascular Outcomes Trial*

We have 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, including cardiovascular death, myocardial infarction, stroke and non-elective coronary revascularization. We enrolled over 9,500 participants at sites in the United States, Canada, Europe, Asia, and Australia with established ASCVD and an LDL-C level of at least 55 mg/dL, and an additional risk enhancer in participants with an LDL-C level below 100 mg/dL, whose LDL-C levels are not adequately controlled despite maximally tolerated lipid-modifying therapies. The planned median trial follow-up is expected to be approximately 42 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 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 designed our PREVAIL trial based on insights gained from analyzing failures of prior CVOTs for other CETP inhibitors. Our trial design targets patients above their LDL-C risk-based goal, despite treatment with maximally tolerated lipid modifying therapies, 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 elevated 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 2.5 years. We believe that the inclusion of a patient population with established ASCVD who are at very high risk to experience a future cardiovascular event given their elevated LDL-C levels despite being treated with maximum lipid lowering therapy and who have other additional 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 3 REMBRANDT Imaging Trial*

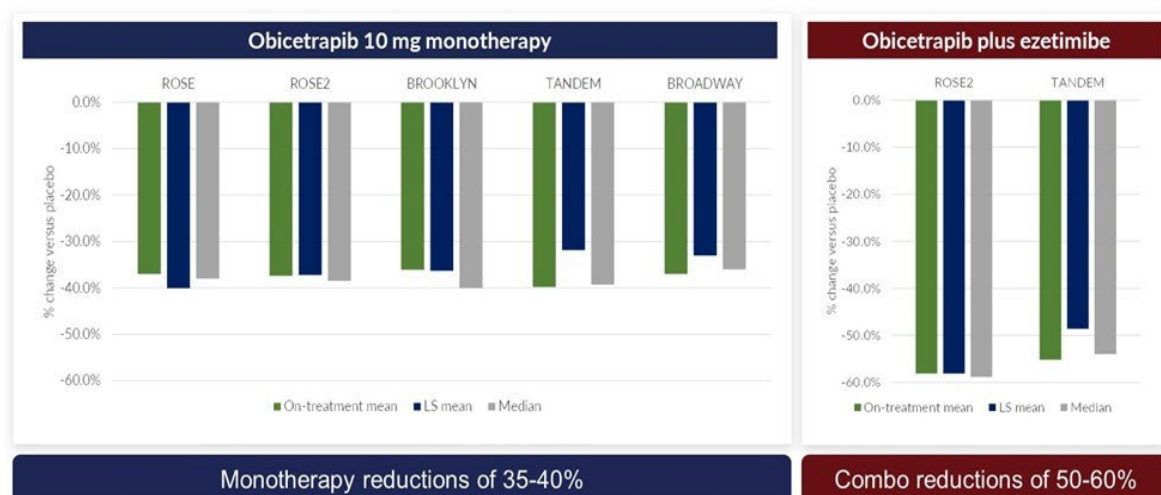
We have initiated REMBRANDT, a Phase 3 cardiovascular computed tomography angiography imaging trial to evaluate the effect of obicetrapib and ezetimibe in fixed-dose combination ("FDC") on coronary plaque. The placebo-controlled, double-blind, randomized, Phase 3 study is being conducted in adult participants with high-risk ASCVD who are not adequately controlled by their maximally tolerated lipid-modifying therapy, to assess the impact of the obicetrapib 10 mg and ezetimibe 10 mg FDC daily on coronary plaque and inflammation characteristics. The study is expected to enroll 300 patients.

### *Phase 2 VINCENT Trial*

VINCENT is a Phase 2 clinical study to evaluate the effects of obicetrapib alone and in combination with evolocumab on Lp(a) in patients with mild dyslipidemia. The single arm study will treat patients with obicetrapib 10 mg daily for 8 weeks followed by obicetrapib 10 mg daily plus evolocumab 140 mg/dL every other week for 8 weeks. There will be two cohorts in the study. The first cohort will include 39 participants with Lp(a) levels greater than 50 mg/dL or 125 nmol/L, and the second cohort will include 30 participants with Lp(a) levels greater than 20 mg/dL or 50 nmol/L but less than 50 mg/dL or 125 nmol/L.

## Completed Phase 3 Clinical Trials

We have completed three Phase 3 clinical trials of obicetrapib for the treatment of cardiometabolic disease. TANDEM evaluated 10 mg obicetrapib and 10 mg ezetimibe as a fixed-dose combination, while BROADWAY and BROOKLYN were designed to measure the effect of obicetrapib 10 mg as monotherapy on top of maximally tolerated lipid-modifying therapy.



### Phase 3 TANDEM Fixed-Dose Combination Trial

We completed TANDEM, a Phase 3 pivotal trial, to evaluate 10 mg obicetrapib and 10 mg ezetimibe as a fixed-dose combination used as an adjunct to diet and maximally tolerated lipid-lowering therapies to potentially enhance LDL-lowering in patients with HeFH, ASCVD or ASCVD risk equivalents in November 2024. We enrolled approximately 400 patients in the United States that had a baseline LDL-C of  $\geq 70$  mg/dL. Following a 14-day screening period, patients were randomized 1:1:1:1 to obicetrapib 10 mg and ezetimibe 10 mg FDC, obicetrapib 10 mg monotherapy, ezetimibe 10 mg monotherapy or placebo for an 84-day treatment period.

TANDEM's co-primary endpoints were percent change from baseline in LDL-C of the fixed-dose combination compared to each monotherapy arm after 84 days and obicetrapib 10 mg compared to placebo after day 84. Secondary endpoints incorporated percent changes from baseline in other biomarkers, including Lp(a), non-HDL-C and ApoB. The TANDEM trial met all co-primary endpoints. The safety and tolerability profile of the fixed-dose combination was observed to be comparable to placebo in the trial.

We believe that the stronger observed LDL-C lowering among patients receiving the combination therapy as compared with those receiving ezetimibe in combination with statin therapy is potentially due to the synergistic mechanisms of action for each of obicetrapib and ezetimibe. While obicetrapib is designed to promote the expression of LDL receptors in the liver, there is evidence that CETP inhibition also promotes cholesterol excretion into the intestines, where ezetimibe is designed to block cholesterol reabsorption into the body. Therefore, the combined mechanism is expected to synergistically enhance fecal sterol removal of cholesterol. We believe that LDL-C lowering effects of ezetimibe can be enhanced by introducing obicetrapib to help facilitate this synergistic mechanism of action.

LDL-C percentage change:

|                                | <b>Ezetimibe<br/>(n=101)</b> | <b>Obicetrapib<br/>(n=102)</b> | <b>Obicetrapib and<br/>Ezetimibe FDC<br/>(n=102)</b> |
|--------------------------------|------------------------------|--------------------------------|------------------------------------------------------|
| <b>Day 84 – from placebo</b>   |                              |                                |                                                      |
| <b>Mean %</b>                  | -23.3                        | -35.5                          | <b>-52.2</b>                                         |
| <b>Median %</b>                | -22.6                        | -37.2                          | <b>-54.0</b>                                         |
| <b>LS mean %</b>               | -20.7                        | -31.9                          | <b>-48.6</b>                                         |
| <b>Comparison to pbo</b>       | -                            | (p<0.0001)                     | <b>(p&lt;0.0001)</b>                                 |
| <b>Comparison to eze 10 mg</b> | -                            | -                              | <b>(p&lt;0.0001)</b>                                 |
| <b>Comparison to obi 10 mg</b> | -                            | -                              | <b>(p=0.0007)</b>                                    |

### *Phase 3 BROADWAY and BROOKLYN Lipid Trials*

We conducted two Phase 3 pivotal trials designed to measure obicetrapib's LDL-C lowering capability and enrolled patients across both trials who require additional LDL-lowering on top of their maximum tolerated lipid-modifying therapies. BROADWAY, which completed enrollment in July 2023 and for which topline results were announced in December 2024, randomized approximately 2,500 patients in the United States, Europe and Asia with 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). BROOKLYN, which completed enrollment in April 2023 and for which topline results were announced in July 2024, enrolled HeFH patients in the United States, Canada, Europe and Africa who had baseline LDL-C of at least 70 mg/dL. Obicetrapib was 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 included 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 was percent change from baseline in LDL-C of obicetrapib 10 mg compared to placebo after 84 days. Secondary endpoints also included percent changes from baseline of obicetrapib 10 mg compared to placebo after 84 days in Lp(a), ApoB, HDL-C and non-HDL-C (representing total cholesterol minus HDL-C), and for BROADWAY, LDL-C levels at days 180 and 365, total cholesterol and triglycerides. For BROADWAY, other exploratory outcome measures included time from randomization until first confirmed occurrence of MACE in the obicetrapib arm compared to placebo. The safety and tolerability profile of obicetrapib was comparable to placebo in both trials (which included a broad representation 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. In addition, we evaluated obicetrapib's effects on blood pressure and no difference from placebo was shown.

The tables below summarize data from each study:

LDL-C LS mean percentage change in BROOKLYN trial:

|                | % Change from Baseline |                        | Obicetrapib % Change |         |
|----------------|------------------------|------------------------|----------------------|---------|
|                | Placebo<br>(n=118)     | Obicetrapib<br>(n=236) | Compared to Placebo  | p-value |
| <b>Day 84</b>  | +0.3%                  | -36.1%                 | -36.3%               | <0.0001 |
| <b>Day 365</b> | +10.3%                 | -31.1%                 | -41.5%               | <0.0001 |

LDL-C percentage change at day 84 in BROADWAY trial:

|                              | Placebo<br>(n = 844) | Obicetrapib 10<br>mg<br>(n = 1686) | Difference  |
|------------------------------|----------------------|------------------------------------|-------------|
| Mean                         | -2%                  | -35%                               | <b>-33%</b> |
| Median                       | -4%                  | -40%                               | <b>-36%</b> |
| LS mean (with<br>imputation) | +3%                  | -30%                               | <b>-33%</b> |

While BROADWAY was not designed or powered to measure MACE benefit, MACE was evaluated as an exploratory endpoint and as part of our safety analysis. Despite the limitations of the trial design, we observed a 21% reduction in MACE favoring obicetrapib after one year.

MACE from BROADWAY:

|                                | Placebo<br>(n = 844) | Obicetrapib 10 mg<br>(n= 1686) | Hazard<br>Ratio | 95% CI      |
|--------------------------------|----------------------|--------------------------------|-----------------|-------------|
| All-cause mortality – no. (%)  | 12 (1.4)             | 19 (1.1)                       | 0.83            | (0.40-1.71) |
| Coronary heart death – no. (%) | 5 (0.6)              | 8 (0.5)                        | 0.80            | (0.26-2.44) |
| First 4-point MACE – no. (%)   | 44 (5.2)             | 70 (4.2)                       | 0.79            | (0.54-1.15) |

4-point MACE: CHD death, non-fatal myocardial infarction, non-fatal stroke, coronary revascularization. MACE was not a primary or secondary endpoint of the BROADWAY trial.

Pooled MACE from BROADWAY and BROOKLYN:

|                                       | Placebo<br>(n = 962) | Obicetrapib 10 mg<br>(n= 1920) | Hazard<br>Ratio | 95% CI             |
|---------------------------------------|----------------------|--------------------------------|-----------------|--------------------|
| <u>All-cause mortality – no. (%)</u>  | <u>14 (1.5)</u>      | <u>20 (1.0)</u>                | <u>0.78</u>     | <u>(0.39-1.58)</u> |
| <u>Coronary heart death – no. (%)</u> | <u>7 (0.7)</u>       | <u>9 (0.5)</u>                 | <u>0.63</u>     | <u>(0.24-1.70)</u> |
| <u>First 4-point MACE – no. (%)</u>   | <u>49 (5.1)</u>      | <u>75 (3.9)</u>                | <u>0.75</u>     | <u>(0.53-1.08)</u> |

4-point MACE: CHD death, non-fatal myocardial infarction, non-fatal stroke, coronary revascularization. MACE was not a primary or secondary endpoint of the BROADWAY or BROOKLYN trials.

Neither the BROADWAY nor BROOKLYN trials were designed to assess MACE as the primary or secondary endpoints and as a result there are limitations on the results presented above. We

are conducting PREVAIL, our Phase 3 cardiovascular outcomes trial designed to assess the MACE benefit of obicetrapib, to provide support for obicetrapib's potential MACE benefit.

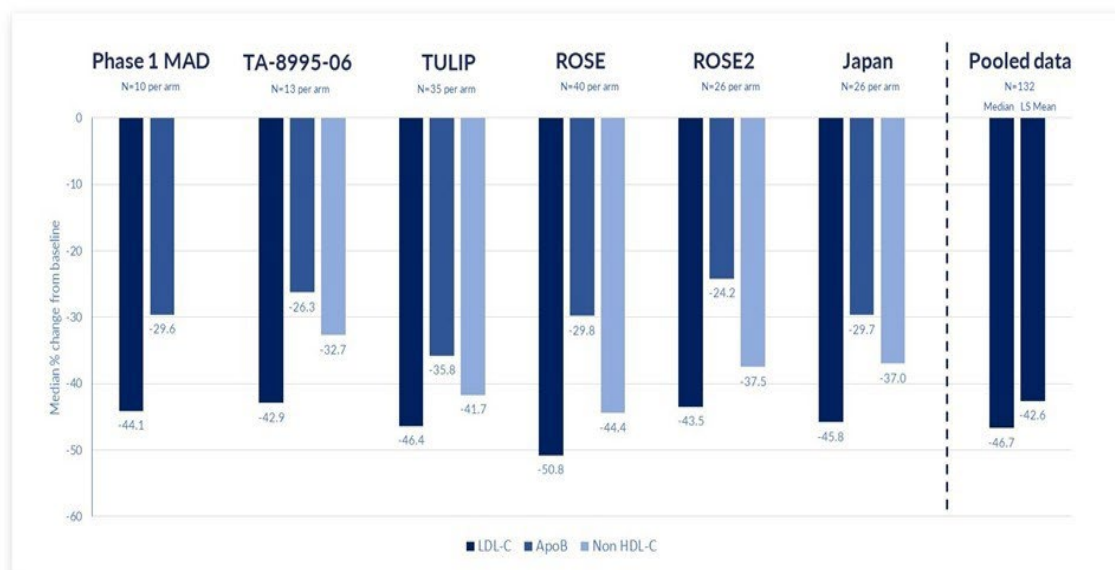
Overall, obicetrapib was observed to be well-tolerated compared to placebo. Treatment-emergent adverse events ("TEAEs") were reported by 1,007 (59.8%) patients in the obicetrapib 10 mg group compared to 513 (60.9%) patients in the placebo group. Most TEAEs were mild or moderate. Treatment-emergent serious adverse events ("TESAEs") were observed in 13.9% of the placebo group and in 12.5% of the obicetrapib group. The following table summarizes the safety results from the BROADWAY trial:

|                                                           | <b>Placebo</b> | <b>Obicetrapib 10 mg</b> |
|-----------------------------------------------------------|----------------|--------------------------|
|                                                           | <b>N= 843</b>  | <b>N= 1,685</b>          |
|                                                           | <b>n (%)</b>   | <b>n (%)</b>             |
| <b>Any TEAEs</b>                                          | 513 ( 60.9)    | 1,007 ( 59.8)            |
| <b>Any TEAEs by maximum severity</b>                      |                |                          |
| Mild                                                      | 228 ( 27.0)    | 481 ( 28.5)              |
| Moderate                                                  | 217 ( 25.7)    | 408 ( 24.2)              |
| Severe                                                    | 68 ( 8.1)      | 118 ( 7.0)               |
| <b>Any trial drug related TEAEs</b>                       | 39 ( 4.6)      | 76 ( 4.5)                |
| <b>Any trial drug-related TEAEs by maximum severity</b>   |                |                          |
| Mild                                                      | 25 ( 3.0)      | 51 ( 3.0)                |
| Moderate                                                  | 14 ( 1.7)      | 23 ( 1.4)                |
| Severe                                                    | 0 ( 0.0)       | 2 ( 0.1)                 |
| <b>Any TEAEs leading to discontinuation of trial drug</b> | 43 ( 5.1)      | 68 ( 4.0)                |
| <b>Any TESAEs</b>                                         | 117 ( 13.9)    | 211 ( 12.5)              |
| <b>Any treatment-emergent non-serious AEs</b>             | 495 ( 58.7)    | 959 ( 56.9)              |
| <b>Any trial drug-related TESAEs</b>                      | 0 ( 0.0)       | 1 ( 0.1)                 |
| <b>Any TEAEs leading to death</b>                         | 12 ( 1.4)      | 19 ( 1.1)                |

### ***Completed Phase 2 Clinical Trials***

We have completed five Phase 2 trials of obicetrapib for the treatment of cardiometabolic disease. In our Phase 2 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 TEAEs were mild or moderate in severity and there were no drug-related, treatment-emergent serious AEs. The graphs below summarize the results of our Phase 1 MAD and Phase 2 trials, with 10 mg of obicetrapib.



### Phase 2b ROSE Trial

In our Phase 2b ROSE trial, we observed that obicetrapib has robust LDL-C 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.

### Phase 2a TULIP Trial

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.

A total of 284 (78.2%) patients experienced at least one TEAE, of which 95 (26.2%) experienced a suspected trial 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 (3.6%) patients experiencing a severe TEAE, two of which were suspected to be related to the trial 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 TESAE, none of which were trial drug related, and no deaths occurred during the trial.

### *Phase 2b ROSE Trial*

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 trial and remaining relatively steady for the remaining four weeks of the trial. 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.

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 (37.5%) subjects in the 5 mg group and 8 (20.0%) subjects in the 10 mg group, compared with 19 (47.5%) subjects in the placebo group. For all treatment groups, the most common TEAEs were fatigue (4.2%), arthralgia (2.5%), nausea (2.5%) and headache (2.5%). 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 trial 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.

### *Phase 2b OCEAN Trial*

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.

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 4 (14.3%) subjects in the obicetrapib 5 mg group and 9 (33.3%) subjects in the combination group, compared with 8 (28.6%) subjects in the ezetimibe 10 mg group and six subjects in the placebo group. For all treatment groups, the most common TEAEs were diarrhea (3.6%), headache (3.6%), myalgia (1.8%) and constipation (1.8%). All other TEAEs were experienced by one or no subjects in each treatment group. TEAEs that were considered to be related to trial 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 trial 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.

### ***ROSE2 Clinical Trial***

On June 3, 2023, we announced full results from our Phase 2 ROSE2 trial, our clinical trial evaluating obicetrapib in combination with ezetimibe as an adjunct to high-intensity statin therapy. ROSE2 met its primary and secondary endpoints, with statistically significant reductions in LDL-C and ApoB observed. Statistically significant improvements in non-HDL-C and total and small LDL-P were also observed. We also observed significant improvements in Lp(a). In addition, the combination of obicetrapib and ezetimibe was observed to be well-tolerated, with a safety profile observed to be comparable to placebo.

ROSE2 was designed as a placebo-controlled, double-blind, randomized Phase 2 clinical trial to evaluate the efficacy, safety and tolerability of obicetrapib 10 mg in combination with ezetimibe 10 mg as an adjunct to high-intensity statin therapy. Patients were randomized to receive combination therapy, obicetrapib 10 mg or placebo for a 12 week treatment period. A total of 119 patients enrolled in ROSE2, of whom 97 were included in the on-treatment analysis. Certain patients were excluded from the on treatment population as a result of suspected non-adherence to the trial protocol. Patients presented at baseline with a fasting LDL-C greater than 70 mg/dL and triglycerides less than 400 mg/dL and all were receiving a stable dose of high-intensity statin therapy.

The primary endpoint was the percent change from baseline to week 12 in Friedewald-calculated LDL-C for the obicetrapib plus ezetimibe combination treatment group compared with placebo. Secondary efficacy endpoints included the percent changes from baseline to week 12 in LDL-C for obicetrapib monotherapy compared with placebo and in ApoB for the obicetrapib plus ezetimibe combination compared with placebo and the obicetrapib monotherapy compared with placebo. Exploratory endpoints included the percent changes from baseline to week 12 in lipoprotein(a), non-HDL-C, HDL-C, total and small LDL-P assessed by NMR, and the proportion of patients at the end of treatment who achieved LDL-C levels below 100 mg/dL, 70 mg/dL and 55 mg/dL for the obicetrapib plus ezetimibe combination and obicetrapib monotherapy groups compared with placebo.

Overall, obicetrapib alone and in combination with ezetimibe was observed to be well-tolerated compared to placebo. TEAEs were reported by 11 (27.5%) subjects in the combination group, 8 (20.5%) subjects in the monotherapy group and 16 (40.0%) subjects in the placebo group. For all treatment groups, the most common AEs nausea (3.4%), urinary tract infection (2.5%), and headache (2.5%). Overall, no drug-related, TESAEs were observed, and there were no TEAEs leading to death. One subject in the combination group had a TEAE leading to discontinuation of the trial drug, compared to two in the monotherapy group and two in the placebo group. There were two severe TEAEs in the placebo group (both nervous system disorders) and one in the monotherapy group (a cardiac disorder).

In parallel with the ROSE2 trial, we formulated two prototype fixed-dose combination tablets of obicetrapib and ezetimibe. These formulations were compared to the co-administration of obicetrapib and ezetimibe in a pilot bioequivalence trial, which was completed in the first half of 2023. Based on the results of this pilot bioequivalence trial and the data and learnings from our ROSE2 trial, we have selected a formulation for a fixed-dose combination tablet of obicetrapib and ezetimibe and initiated TANDEM, a Phase 3 pivotal trial, to evaluate 10 mg obicetrapib and 10 mg ezetimibe as a fixed-dose combination used as an adjunct to diet and maximally tolerated lipid-lowering therapies to potentially enhance LDL-lowering in patients with HeFH, ASCVD or ASCVD risk equivalent patients, in the first quarter of 2024 and released topline data in November 2024.

## ***Japan Phase 2b Clinical Trial***

On June 5, 2023, we announced topline results from our Phase 2b Japan trial evaluating the effects of three doses of obicetrapib (2.5 mg, 5 mg, and 10 mg) on LDL-C levels. This was a randomized, double-blind, placebo controlled trial designed to evaluate the efficacy, safety and tolerability of obicetrapib as an adjunct to stable statin therapy in Japanese patients. The trial was conducted at hospitals and clinics across Japan. The primary endpoint was the percent change from baseline to end of treatment (day 56) in LDL-C for each obicetrapib group compared to placebo. The trial enrolled 102 adult participants, who were randomized 1:1:1:1 to receive obicetrapib 2.5 mg, 5 mg, 10 mg or placebo for the 56-day treatment period. Patients treated with obicetrapib 2.5 mg, 5 mg or 10 mg achieved a median reduction in LDL-C of 24.8%, 31.9%, and 45.8%, respectively, as compared to patients treated with placebo, who achieved a median reduction in LDL-C of 0.9%. In addition, patients treated with obicetrapib 10 mg achieved a median reduction in ApoB of 29.7%, compared to a 0.4% reduction in patients treated with placebo, and a median reduction in non-HDL-C of 37.0%, as compared to a 0.4% reduction in patients treated with placebo. The p-value for each endpoint in the obicetrapib arms of the trial compared to placebo was <0.0001. Overall, the different dosages of obicetrapib were observed to be generally well-tolerated, with a safety profile comparable to placebo. TEAEs were reported by 15 (57.7%) subjects in the 10 mg obicetrapib group, 7 (28.0%) subjects in the 5 mg obicetrapib group, 9 (36.0%) subjects in the 2.5 mg group and 15 (57.7%) subjects in the placebo group. AEs observed to date were primarily mild. One TESA was observed in the 5 mg group, but it was not considered by the investigator to be related to trial treatment. Overall, no drug-related TESA were observed, and there were no TEAEs leading to death.

## ***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 ("A $\beta$ ") peptide removal from brain parenchyma 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 brain parenchyma for ultimate conversion and transport out of the brain.

Alzheimer's disease, however, is characterized in part by the aggregation of A $\beta$  peptides into amyloid plaques in brain parenchyma, facilitated by the presence of excess cholesterol in cell membranes. Thus, the accumulation of cholesterol in cell membranes and the ineffective clearance of A $\beta$  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 in the circulation observed in our Phase 2 clinical trials and the increases in ApoE in the circulation observed in the TULIP trial, we have conducted preclinical assessments of obicetrapib for the 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 the prevention and treatment of Alzheimer's disease. We commenced a Phase 2a open-label and single-arm 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. A total of 13 patients were given 10 mg obicetrapib and followed for 24 weeks. In September 2023, we announced initial data from this trial. We observed reductions in the levels of 24-hydroxycholesterol and 27-hydroxycholesterol of 11% and 12%, respectively, in the CSF compared to baseline. In addition, an increase of 8% compared to baseline in the A $\beta$ 42/40 ratio in patient's plasma was observed and pTau181 levels were observed to be stable. Increases in 24-hydroxycholesterol and 27-hydroxycholesterol over time have been observed previously to lead to a rise in cognitive and related functional impairment. We believe reductions of these oxysterols in the CSF may indicate improved cholesterol metabolism in the brain and may lead to improved cognitive function. In addition, this trial assessed the A $\beta$ 42/40 ratio and plasma pTau181, also believed to be biomarkers of Alzheimer's disease, with lower levels of A $\beta$ 42/40 and increased levels of pTau181 having been associated with a greater risk of Alzheimer's disease. Overall, obicetrapib was observed to be well-tolerated. No serious AEs were reported, nor were any AEs considered to be related to the trial drug.

## **Manufacturing and Supply**

We currently have no manufacturing facilities and instead rely on several contract manufacturers to produce drug substance and drug products. The production is overseen by an experienced group of personnel. Obicetrapib and obicetrapib and ezetimibe FDC tablets are manufactured and tested in accordance with current good manufacturing practices ("cGMPs") at facilities in the United States, Canada and Austria. In preparation for commercial supply, we are in the process of expanding our supply network to support a commercial launch of obicetrapib, if approved.

## **Marketing and Sales**

While we do not currently have the internal marketing, sales or distribution capabilities necessary to commercialize obicetrapib or any future product candidates, if approved for commercial sale, we are currently developing our own commercial infrastructure and capabilities in the United States and have entered, and expect to continue entering, 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 entered into the Menarini License, 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 or with a partner.

## *Menarini License*

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, of which a total of €30 million has been received to date. 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 obicetrapib and ezetimibe FDC tablets 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 products for the Menarini Territory as set forth in the Supply Agreement.

In the year ended December 31, 2024, we received one milestone payment from Menarini under the Menarini License upon the achievement of a clinical milestone.

## **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, 2024, we owned 10 issued U.S. patents and 17 pending U.S. patent applications. We also owned 132 granted European patents and five pending European patent applications, two granted Chinese patents and 12 pending Chinese patent applications. In addition, we owned 77 granted patents and 70 pending patent applications in other foreign jurisdictions, including international applications under the 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 Hatch-Waxman Amendments 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 the IND for the first investigation involving human beings and the submission date of an NDA seeking FDA approval, plus the entire time from submission date of the NDA to 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, an approved method for using the approved product, 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 “*Risk Factors—Risks Related to Our Intellectual Property*.”

The issued patents and pending patent applications for obicetrapib as of December 31, 2024 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. In Europe, we have 17 granted patents. 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 also 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. Patents 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 in this latter patent family. 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 four granted patents in the United States and a pending application. We have 39 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 15 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 various foreign jurisdictions, methods of use in which obicetrapib and a statin are separately administered. We have one granted patent in the United States. This patent is expected to expire in February 2034. We have no granted patents in Europe. In Asia, we have no granted patents in China, two granted patents in Japan, one granted patent in the Republic of Korea and two granted patents in Taiwan. 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 two granted patents in other foreign jurisdictions. Patent applications are pending in China, Hong Kong,

Thailand and Venezuela. Outside the United States, patents and patent applications, if granted, are expected to expire in 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 a 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 Republic of Korea and one granted patent in Taiwan. We also 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 15 granted patents in other foreign jurisdictions. Patent applications are pending in Europe, Hong Kong 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 a third generation patent family covering the solid salt form of obicetrapib that we intend to commercialize, a process for its commercial synthesis and a novel intermediate used in that synthetic process. In the United States, we have an issued patent with claims covering the solid salt form of obicetrapib, and a pending application. Patent applications are pending worldwide in over 40 jurisdictions. Our U.S. patent, and patents if granted on the pending applications, are expected to expire in July 2043, without taking potential patent term adjustment or extensions into account.

We also have patent families directed to various compositions and methods of use of obicetrapib as a combination therapy. These families all consist of pending applications. Seven of these families are directed to combinations with ezetimibe, several of which cover the formulation of our intended commercial fixed-dose combination product. Two of these families further include the commercial formulation of our intended obicetrapib single active product. Patents if granted are expected to expire between February 2042 and November 2045, without taking potential patent term adjustment or extensions into account. Another family is directed to a combination with statins, for use in certain subpopulations. Patents if granted are expected to expire in July 2042, without taking potential patent term adjustment or extensions into account. We also have two families directed to combinations with SGLT2 inhibitors. If granted, these patents are expected to expire in December 2042 and April 2044, without taking potential patent term adjustment or extensions into account.

We have an additional patent family directed to a new process for synthesis of an intermediate in the manufacture of obicetrapib. This family currently consists of a U.S. provisional application. Any patents, if granted, are expected to expire about November 2045.

We have two patent families respectively covering treatment of the patient populations enrolled in our BROOKLYN and BROADWAY trials. These families currently consist of pending applications. Patents if granted on these applications are expected to expire approximately in September 2044 and September 2045. We also have a patent family directed to reductions in atherosclerotic plaque which currently consists of a pending PCT application. Patents if granted in this family are expected to expire in December 2044.

In addition, we have two patent families covering methods of using obicetrapib to treat neurodegenerative diseases. The first of these families includes 31 granted patents in Europe, one granted patent in Hong Kong and one granted patent in Israel. We also have patent applications pending in this family in the United States, Europe, China and other jurisdictions. The granted patents, and patent applications if granted, are expected to expire in March 2042, without taking potential patent term

adjustment or extensions into account. The second family consists of a PCT application and a pending U.S. provisional application. Any patents that grant from this second family are expected to expire in September 2044, without taking potential patent term adjustments or patent term extensions into account.

Finally, we have three patent families drawn to treatment of other clinical indications. Patents if granted from these families will expire in about October 2044, without taking potential patent term adjustments or patent term extensions into account.

### ***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 “*Risk Factors—Risks Related to Our Intellectual Property.*”

### **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, clinical trials 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 Federal Food, Drug, and Cosmetic Act (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 (“GLP”) requirements and other applicable regulations;

- submission to the FDA of an Investigational New Drug (“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 investigational review board (“IRB”) or independent ethics committee (“EC”) at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice (“GCP”) regulations, 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 trials 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 trials. 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 trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, 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 trial until completed. Some trials also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board, which provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial 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 trials and clinical trial 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 trials 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 trials 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 trials 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 trials intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including trials 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 trials 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 trials or surveillance programs.

In addition, the Pediatric Research Equity Act (“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 the 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 trials 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 trials or if such trials 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 abbreviated new drug application (“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, the FDA must issue a Written Request detailing the trials to be performed and the timeframe for their completion. If an applicant agrees to perform the trials as outlined in the Written Request, the applicant must submit trial reports at least nine months prior to the expiry of the exclusivity that is to be extended. The trial 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 in the event of a deviation. 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 trials or clinical trials 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 trials;
- 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 promotional 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 labeling.

#### *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 federal False Claims Act (the "FCA"), 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 FCA may be brought by the U.S. 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 civil FCA.

In addition, the civil monetary penalties statute, subject to certain exceptions, prohibits, among other things, the offer or transfer of remuneration 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.

The federal Health Insurance Portability and Accountability Act of 1996 (“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, imposes 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 applicable 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 (“CMS”), 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 CMS ownership and investment interests held by physicians and their immediate family members.

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 and the reimbursement of drug products. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act (the "IRA") into law which sets forth meaningful changes to drug product reimbursement by Medicare. The IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered 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 began to take effect in 2023, although several significant challenges concerning the provisions for Medicare price negotiations are currently pending before federal appeals courts. With

respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B or Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or D drugs in 2028 and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least 7 years and biologics that have been licensed for 11 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. CMS may establish a maximum price for these products in price negotiations.

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 price 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.

These provisions of the IRA may heighten the risk that we would not be able to achieve the expected return on our drug products or full value of our patents protecting our products.

In addition as a result of the Budget Control Act of 2011, health care providers are subject to Medicare payment reductions of 2% per fiscal year. This 2% reductions 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 types of 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 first 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 eliminated the statutory Medicaid drug rebate price cap as of 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.

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, the California Privacy Rights Act and the European General Data Protection Regulation 2016/679 ("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. Privacy and security laws, regulations and other obligations are constantly evolving, and these may conflict with each other which makes compliance efforts more challenging. Failure to comply with these laws, where applicable, can result in (i) the imposition of significant civil claims; (ii) private litigation; (iii) regulatory investigations and proceedings; (iv) significant penalties imposed by regulators; (v) enforcement notices

and restrictions on data processing, requiring us to stop or change the way we use personal information; and (vi) negative publicity, reputational harm and a potential loss of business and goodwill.

### *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, manufacturing 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.

Medicinal products in the EU must be granted a marketing authorization (“MA”) before they can be marketed and sold in any EU member state. The process to obtain an MA requires the 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 an EU marketing authorization application (“MAA”) and granting of an MA by these authorities. The aforementioned EU rules are 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, the authorization 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 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. Research involving animals conducted within the EEA must comply with relevant national implementations of Directive 2010/63/EU, requiring that such testing is carried out in licensed facilities with appropriate staff and in compliance with animal welfare standards.

Until recently, the Clinical Trials Directive 2001/20/EC, the Directive 2005/28/EC on GCP, the Directive 2003/94/EC on GMP and the related national implementing provisions of the individual EU member states governed the system for the approval of clinical trials and the investigational medicinal product supply chain in the EU. As of January 31, 2022, the new Clinical Trials Regulation (EU) No 536/2014 took effect and replaced the Clinical Trials Directive 2001/20/EC. Commission Implementing Regulation (EU) 2017/556 replaces the GCP Directive 2005/28/EC, and Commission Delegated Regulation (EU) 2017/1569 replaces the GMP Directive 2003/94/EC with respect to investigational medicinal products. Pursuant to transitional provisions under the Regulation, qualifying trials could continue to be governed by the national implementations of the Directives until January 31, 2025 if (i) a request for approval was submitted prior to January 31, 2022 or (ii) a request for approval was submitted prior to January 31, 2023 and the sponsor elected to follow the national implementations of the Directives instead of the Regulation. All ongoing clinical trials in the EU will be subject to the requirements of the Regulation after January 31, 2025.

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 Clinical Trials Information System; a single set of documents to be prepared and submitted for the application, as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is jointly 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, if intended for regulatory submissions, 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 EEA, it must appoint an entity within the EEA 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 EEA member states in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific trial 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, including in accordance with Commission Delegated Regulation (EU) 2017/1569.

### *EU Marketing Authorizations*

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

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, and by extension also in the three EEA 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 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.

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.

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 report and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report and related materials are 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 potentially 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 ("CMDh") for review. The CMDh seeks to resolve the issue by achieving a negotiated consensus amongst participating member states. If that is not possible, the issue may be referred to the CHMP. The CHMP will allow submissions from the applicant and, having considered the relevant issues and data, will issue an opinion by majority vote. The Committee will then send the opinion to the European Commission, which will adopt a decision that is binding on the applicant and all EU relevant 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, any EU 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 that 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).

In the EU, a “conditional” MA may be granted to meet the unmet medical needs of patients for medicinal products intended for the treatment, prevention or medical diagnosis of seriously debilitating or life-threatening diseases 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 trials) and the complete data confirm that the medicinal product's benefits continue to outweigh its risks, the conditional MA can be converted into a standard MA. However, if the specific obligations are not fulfilled within the timeframe set by the EMA, the conditional MA may 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 for medicinal products intended to be authorized for the 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. While an MA under exceptional circumstances may be subject to an obligation to conduct post-approval studies, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not required to provide the missing data on the medicinal product’s efficacy and safety necessary to convert the conditional MA into a standard MA. Subject to renewal after five years (as with all standard MAs), the MA “under exceptional circumstances” is granted definitively, but 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 EEA requires a manufacturing authorization, and import of medicinal products into the EEA 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 active pharmaceutical ingredients (“API”), 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 good distribution practice (“GDP”) standards and 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 the MA, MIA or distribution authorization, in case of non-compliance with the EU or EU member states’ requirements applicable to the manufacturing, import and distribution of medicinal products.

#### *EU Data and Market Exclusivity*

The EU provides opportunities for data and market exclusivity related to MAs. Upon receiving an initial MA, innovative medicinal products that comprise a new active substance are entitled to eight years of data exclusivity and ten years of market exclusivity. Data exclusivity, if granted, prevents generic or biosimilar product manufacturers from referencing the innovator’s preclinical and clinical data in generic or biosimilar MAAs 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 an innovative medicinal product will be considered by the EU’s regulatory authorities to be a new active substance eligible for data and market exclusivity. These periods of data and market exclusivity may also be granted for a new MA for an existing active substance

if the applicant is unrelated to the original MA holder and the MAA comprises a full free-standing dossier with relevant preclinical and clinical data

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 biosimilarity must be provided in support of an MAA.

In April 2023, the European Commission proposed widespread changes to the existing pharmaceutical legislation that would, among other things, alter the data exclusivity periods available to MA holders if adopted into EU law.

### *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 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 trials.

In the EU, the advertising and the 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 the general requirements for the advertising and the promotion of medicinal products are established under EU directives, the details are governed by laws and regulations in each member state and can differ from one country to another. For example, applicable laws prohibit pre-authorization and misleading advertising and 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 are inexpensive and relevant to the practice of medicine.

### *Proposals to amend EU pharmaceutical laws*

In April 2023, the European Commission released proposals to amend the current EU pharmaceutical regulatory framework. The proposals seek to achieve a balance between supporting innovation and increasing the affordability and geographic availability of medicines. The potential reforms include shortening and modulating the periods of regulatory and/or marketing protections available for innovative products, requiring applicants to include environmental impact assessments in MAAs, increasing transparency and disclosure requirements, and restructuring the EMA's scientific committees. The European Parliament adopted its position on the proposals on April 10, 2024 and the European Council is expected to adopt its position in 2025. Further trialogue negotiations between the European Commission, European Parliament and the European Council will then begin before the proposed reforms can enter into force under EU legislative procedures. Depending on the progress of these negotiations, legislative changes, if any, are not expected to come into force until 2026 at the earliest. It is also expected that there will further transition periods for most, if not all, of the new rules once the necessary legislation becomes effective.

### *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 EU. 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 guidelines. 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 preclinical 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 PMDA. This notification must be submitted after obtaining agreement of the 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 cGMPs.

Non-clinical studies performed to demonstrate the safety of new chemical or biological substance must be conducted in compliance with the principles of Japanese 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 and demonstrates unique therapeutic value, the applicant may be able to obtain designation as an orphan drug product. There are also expedited programs for (i) truly innovative products for grave diseases with a unique mechanism of action (provided that development in Japan is concurrent or ahead of other jurisdictions) and (ii) products that satisfy certain 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 application, 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 drug marketing license. 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 drug 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 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, if the drug is already approved abroad, holds 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, rules and guidelines further implementing the DAL. The rule governing CTAs, marketing approval, and post-approval amendment and renewal is known as the Drug Registration Regulation ("DRR").

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 GLP. If the preclinical 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 may 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 certain 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. Prior to consenting subjects, information about clinical trials must be registered on a CDE-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 certain phases 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 can each require a CTA (unless one CTA covers all three). These clinical trials must be conducted in accordance with a protocol that NMPA, various ethics committees at different sites, and the Ministry of Science and Technology (which grants

HGR approvals) all review 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 and sites 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 trials, routine annual reporting, and safety monitoring and reporting of adverse drug reactions, 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.

#### **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 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, Verve Therapeutics and others, that are intended to treat CVD.

## **Sustainability**

We are dedicated to conducting business in a safe and environmentally sustainable manner as part of our commitment to not only improve the lives of patients we hope to serve, but also to positively impact our employees, business partners, and surrounding communities as well. In an effort to do this, we:

- comply with environmental laws and regulations that are related to our specific work and responsibilities;
- encourage employees to respect the environment and natural resources available to us by taking sustainability steps like limiting energy use, reducing waste, and recycling; and
- have awareness and training programs to teach our employees how to deal with different waste systems.

We are committed to expanding and developing our sustainability initiatives in the future. Given the present state of scientific knowledge, it is not possible to examine the complex interactions in a living organism solely by the use of modeling or performing experiments in cell cultures and tissue samples. Research using living animals remains essential in the discovery, development, and production of new medicines. We cannot replace all animal experiments in the foreseeable future, but we continuously review the welfare and use of animals and develop procedures that reduce or replace animal experiments. When we engage in research using live animals, we follow all applicable laws and regulations.

## **Employees and Human Capital Resources**

As of December 31, 2024, we had 68 employees, consisting of clinical, research and development, business development, regulatory, finance and operational personnel. None of our employees are subject to a collective bargaining agreement. We consider our relationship with our employees to be good. In addition, as of December 31, 2024, we engaged a total of 13 independent contractors. These independent contractors provide a diverse array of services, which includes assisting with our clinical development, manufacturing activities and regulatory obligations.

No Works Council or other employee representative body (*personeelsvertegenwoordiging*) is established within the Company, 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 and a 401(k) plan for US employees—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.

The results of litigation and claims cannot be predicted with certainty, and unfavorable resolutions are possible and could materially affect our results of operations, cash flows or financial position. In addition, regardless of the outcome, litigation could have an adverse impact on us because of defense costs, diversion of management resources and other factors.

## 2.3 Organizational structure

As of December 31, 2024, 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 two administrative offices of approximately 1,375 square feet, located at 20803 Biscayne Blvd., Suite #105, Aventura, FL 33180 and approximately 10,476 square feet located at 19 W. College Avenue, Suite 200, Yardley PA 19067. These office spaces house our U.S. administration, human resources, information technology, finance, clinical operations, commercial 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.

## 2.5 Operating results

### Results of Operations

The following table summarizes our consolidated statements of operations for the periods indicated:

|                                                            | <b>For the year ended December 31,</b> |             |
|------------------------------------------------------------|----------------------------------------|-------------|
|                                                            | <b>2024</b>                            | <b>2023</b> |
| <i>(In thousands of USD, except per share amounts)</i>     |                                        |             |
| Revenue                                                    | 45,563                                 | 14,090      |
| Operating expenses:                                        |                                        |             |
| Research and development expenses                          | (152,784)                              | (160,347)   |
| Selling, general and administrative expenses               | (73,220)                               | (38,381)    |
| Total operating expenses                                   | (226,004)                              | (198,728)   |
| Operating loss                                             | (180,441)                              | (184,638)   |
| Other income (expense):                                    |                                        |             |
| Finance income                                             | 16,882                                 | 11,283      |
| Finance expense                                            | (26)                                   | (6)         |
| Loss on debt extinguishment                                | —                                      | —           |
| Fair value change – earnout and warrants                   | (75,593)                               | (10,284)    |
| Fair value change – profit rights                          | —                                      | —           |
| Fair value change – tranche rights                         | —                                      | —           |
| Foreign exchange gains/(losses)                            | (6,598)                                | 5,058       |
| Loss before tax                                            | (245,776)                              | (178,587)   |
| Income tax expense                                         | 1                                      | (27)        |
| Loss for the year                                          | (245,775)                              | (178,614)   |
| Other comprehensive income (loss)                          |                                        |             |
| Foreign currency translation adjustments                   | —                                      | —           |
| Unrealized gain on available-for-sale securities           | 45                                     | —           |
| Income tax effects of other comprehensive income (loss)    | —                                      | —           |
| Total comprehensive income (loss) for the year, net of tax | (245,730)                              | (178,614)   |
| Net loss per ordinary share                                |                                        |             |
| Basic and diluted                                          | \$ (2.60)                              | \$ (2.17)   |

### Revenue

Revenue increased by \$31.5 million, or 223.4%, to \$45.6 million for the year ended December 31, 2024 compared to \$14.1 million for the year ended December 31, 2023. This change is largely due to \$27.3 million of revenue recognized in the year ended December 31, 2024 related to the license performance obligation under the Menarini License for a clinical success milestone compared to \$5.4 million of such revenue recognized in the year ended December 31, 2023. The remainder of the change is due to an increase of \$9.5 million in the revenue recognized related to the R&D performance obligation in the year ended December 31, 2024 as compared to the year ended December 31, 2023. This increase in revenue related to the R&D performance obligation is composed of the following:

- recognition of \$11.9 million of in the year ended December 31, 2024 while no such cost reimbursement was recognized in the year ended December 31, 2023; and
- an offsetting decrease of \$2.3 million in recognition of deferred revenues in the year ended December 31, 2024 as compared to the year ended December 31, 2023 due to differences in the percentage of completion achieved in each respective year related to the performance obligation.

### Research and Development Expenses

Research and development expenses decreased by \$7.6 million, or 5.0%, to \$152.8 million for the year ended December 31, 2024 compared to \$160.3 million for the year ended December 31, 2023. This was primarily driven by:

- a \$10.2 million decrease in manufacturing costs;
- a \$1.1 million decrease in non-clinical expenses related to preclinical studies;
- a \$0.9 million decrease in clinical expenses due to clinical trial which are complete or nearing completion;
- a partially offsetting \$0.9 million increase in regulatory expenses; and
- a partially offsetting \$3.6 million increase in personnel expenses.

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

|                                                | <u>2024</u>             | <u>2023</u>             | <u>Change</u>       |
|------------------------------------------------|-------------------------|-------------------------|---------------------|
| Clinical expenses                              | (105,904)               | (106,770)               | 866                 |
| Non-clinical expenses                          | (1,859)                 | (2,917)                 | 1,058               |
| Personnel expense (see Note 7)                 | (25,397)                | (21,799)                | (3,598)             |
| Manufacturing costs                            | (17,188)                | (27,430)                | 10,242              |
| Regulatory expenses                            | (2,186)                 | (1,297)                 | (889)               |
| Other R&D costs                                | (250)                   | (134)                   | (116)               |
| <b>Total research and development expenses</b> | <b><u>(152,784)</u></b> | <b><u>(160,347)</u></b> | <b><u>7,563</u></b> |

### Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by \$32.8 million, or 87.2%, to \$70.4 million for the year ended December 31, 2024 compared to \$37.6 million for the year ended December 31, 2023. This was primarily driven by:

- a \$25 million increase in personnel expenses related to selling, general and administrative expenses, of which our share-based compensation arrangements account for \$11.9 million. The remainder is largely due to increased recruitment and employment costs for individuals involved with administrative and commercial preparedness activities to support the growth of the organization;
- a \$10.5 million increase in commercial costs related to startup costs as we begin to build capabilities to support our planned commercial launch of obicetrapib, if approved; and
- a partially offsetting \$2.8 million decrease in transaction costs primarily due to costs incurred in 2023 in connection with an underwritten public offering of Ordinary Shares by certain of our shareholders. We did not sell any Ordinary Shares in the offering and did not receive any proceeds from the offering.

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

|                                                           | 2024            | 2023            | Change          |
|-----------------------------------------------------------|-----------------|-----------------|-----------------|
| <b>Included in selling expenses:</b>                      |                 |                 |                 |
| Commission expense                                        | (174)           | (281)           | 107             |
| <b>Included in general and administrative expenses:</b>   |                 |                 | —               |
| Personnel expense (see Note 7)                            | (42,319)        | (17,267)        | (25,052)        |
| Travel costs                                              | (2,025)         | (1,035)         | (990)           |
| Intellectual property                                     | (2,403)         | (1,917)         | (486)           |
| Legal costs                                               | (2,140)         | (2,168)         | 28              |
| Finance and administration                                | (3,421)         | (4,122)         | 701             |
| Transaction costs                                         | (596)           | (3,427)         | 2,831           |
| IT                                                        | (304)           | (111)           | (193)           |
| Rent and office services                                  | (517)           | (227)           | (290)           |
| Marketing and communication                               | (1,981)         | (793)           | (1,188)         |
| Insurance                                                 | (1,815)         | (2,183)         | 368             |
| Depreciation and amortization                             | (236)           | (77)            | (159)           |
| Commercial costs                                          | (12,880)        | (2,382)         | (10,498)        |
| Business development                                      | (223)           | (745)           | 522             |
| Board fees                                                | (431)           | (336)           | (95)            |
| Miscellaneous                                             | (194)           | (200)           | 6               |
| Filing fees                                               | (215)           | (313)           | 98              |
| Consulting fees                                           | (418)           | (176)           | (242)           |
| Conferences                                               | (266)           | (136)           | (130)           |
| Recruitment costs                                         | (662)           | (485)           | (177)           |
| <b>Total selling, general and administrative expenses</b> | <b>(73,220)</b> | <b>(38,381)</b> | <b>(34,839)</b> |

### *Interest Income*

Interest income increased by \$5.6 million, to \$16.9 million for the year ended December 31, 2024 compared to \$11.3 million for the year ended December 31, 2023. This increase was primarily driven by greater cash balances and investments in marketable securities during the year ended December 31, 2024 as compared to cash balances during the year ended December 31, 2023.

### *Fair Value Change - Earnout*

Fair value change - earnout was a loss of \$37.0 million for the year ended December 31, 2024 compared to a loss of \$0.3 million for the year ended December 31, 2023. The change is driven by changes in the market price during the period for Ordinary Shares and an increase in the estimated probability of achieving the earnout milestone from 40% as of December 31, 2023 to 100% as of December 31, 2024.

### *Fair Value Change - Warrants*

Fair value change - warrants was a loss of \$38.6 million for the year ended December 31, 2024 compared to a loss of \$10.0 million for the year ended December 31, 2023. The change is driven by changes in the market price during the period for the Warrants, which trade under the symbol "NAMSW."

### *Foreign Exchange Gains/(Losses)*

Net foreign exchange gains/(losses) were a loss of \$6.6 million for the year ended December 31, 2024 compared to a gain of \$5.1 million for the year ended December 31, 2023. This change was largely driven by a weakening of the Euro against the U.S. Dollar.

### *Loss for the Year*

Loss for the year increased by \$67 million, to \$245.8 million for the year ended December 31, 2024 compared to \$178.6 million for the year ended December 31, 2023. The individual components of the change are described above.

## **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 of December 31, 2024, we had an accumulated loss of \$553.8 million. We expect to continue to incur significant losses for the foreseeable future. We expect to continue incurring significant costs 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 CMOs;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- compensation expenses associated with increased headcount;
- the costs of preparing for launch and commercialization of our product candidate;
- losing our status as a foreign private issuer; 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 and public offerings of shares, the sale of convertible notes, proceeds from the Menarini License and the proceeds from the Business Combination. As of December 31, 2024, we had cash and cash equivalents of \$771.7 million. Until we can generate substantial revenue, 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. In addition to our partnership with Menarini, we may in the future utilize a variety of types of collaboration, license, monetization, distribution and other arrangements with other third parties relating to the development or commercialization, once approved, of obicetrapib or future product candidates or indications. 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 titled "*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. We are also continually evaluating the potential acquisition or license of new product candidates.

## **Sources of Liquidity**

### *December 2024 Follow-on Offering*

On December 13, 2024, we completed the December 2024 Offering of 14,667,347 Ordinary Shares at a public offering price of \$24.50 per Ordinary Share and, in lieu of Ordinary Shares to certain investors, Pre-Funded Warrants to purchase 4,882,653 Ordinary Shares at a public offering price of \$24.4999 per Pre-Funded Warrant, which represents the per share public offering price for the Ordinary Shares, less the \$0.0001 per share exercise price for each such Pre-Funded Warrant. Of the 14,667,347 Ordinary Shares issued and sold in the December 2024 Offering, 2,550,000 Ordinary Shares were issued and sold pursuant to the exercise of the underwriters' option to purchase additional Ordinary Shares at the public offering price per share. The net proceeds to the Company from the December 2024 Offering were \$453.4 million after deducting underwriting discounts and commissions and offering expenses payable by the Company.

### *February 2024 Follow-on Offering*

On February 16, 2024, we completed an underwritten public offering (the "February 2024 Offering") of 5,871,909 Ordinary Shares at a public offering price of \$19.00 per Ordinary Share and, in lieu of Ordinary Shares to certain investors, Pre-Funded Warrants to purchase 4,736,841 Ordinary Shares at a public offering price of \$18.9999 per Pre-Funded Warrant, which represents the per share public offering price for the Ordinary Shares less the \$0.0001 per share exercise price for each such Pre-Funded Warrant. Of the 5,871,909 Ordinary Shares issued and sold in the February 2024 Offering, 1,383,750 Ordinary Shares were issued and sold pursuant to the exercise of the underwriters' option to purchase additional Ordinary Shares at the public offering price per share. The net proceeds to the Company from the February 2024 Offering were \$190.0 million after deducting underwriting discounts and commissions and offering expenses payable by the Company.

### *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 the Licensed Products, for any use in the Menarini Territory. Pursuant to the Menarini License, Menarini made a non-refundable, non-creditable upfront payment

to us of €115 million. Menarini has also committed to providing us €27.5 million in funding for the research and development activities related to the Licensed Products over two 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 €863 million upon the achievement of various clinical, regulatory and commercial milestones, €30 million of which has been received to date. 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 IP payments. See the section titled "*Business—Commercial*" for a full description of the Menarini License.

As of December 31, 2024, we have received a total of €30 million in milestone payments from Menarini, €25 million of which was received in the year ended December 31, 2024.

### *Warrants*

In the year ended December 31, 2024, 1,384,640 Warrants were exercised at an exercise price of \$11.50 per Ordinary Share, generating gross proceeds of \$13.8 million. As of December 31, 2024, we had another 2,632,581 outstanding Warrants to purchase 2,632,581 Ordinary Shares, exercisable at an exercise price of \$11.50 per share, which will expire on November 23, 2027, at 5:00 p.m., Eastern Standard Time. Based on the exercise price of the Warrants, we may receive up to \$30.3 million, assuming the exercise of all Warrants outstanding as of December 31, 2024. The exercise of the Warrants, and any proceeds we may receive from their exercise, are highly dependent on the price of our Ordinary Shares and the spread between the exercise price of the Warrant and the price of an Ordinary Share at the time of exercise. For example, to the extent that the trading price of the Ordinary Shares exceeds \$11.50 per share, it is more likely that holders of our Warrants will exercise their Warrants. If the trading price of the Ordinary Shares is less than \$11.50 per share, it is unlikely that such holders will exercise their Warrants. The exercise price of the Warrants has at times exceeded the market price of the Ordinary Shares. To the extent that the price of our Ordinary Shares is below \$11.50, we believe that the Warrant holders will be unlikely to cash exercise their warrants, resulting in little to no cash proceeds to us. There can be no assurance that our Warrants will be in the money prior to their expiration and, as such, certain unexercised Warrants may expire worthless. As such, it is possible that we may never generate any additional cash proceeds from the exercise of our Warrants. We have not included, and do not intend to include, any potential cash proceeds from the exercise of our Warrants in our short-term or long-term liquidity projections. We will continue to evaluate the probability that the Warrants are exercised over the life of our Warrants and the merit of including potential cash proceeds from the exercise thereof in our liquidity projections.

### *Business Combination and PIPE Financing*

In July 2022, we entered into a Business Combination Agreement with FLAC, NewAmsterdam Pharma and Merger Sub, which closed on November 22, 2022.

Concurrently with the execution of the Business Combination Agreement, we and FLAC also entered into Subscription Agreements with certain investors, pursuant to which the PIPE Investors agreed to subscribe for and purchase from us, and we 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 closed substantially concurrently with the Business Combination.

We received an aggregate of \$306.3 million from the Business Combination and associated PIPE Financing at the closing of the Business Combination, prior to deducting the \$2.6 million of transaction costs directly attributable to these financing activities.

## Cash Flows

|                                                         | For the year<br>ended December 31, |                |
|---------------------------------------------------------|------------------------------------|----------------|
|                                                         | 2024                               | 2023           |
|                                                         | (USD in thousands)                 |                |
| Net cash flows used in operating activities             | (158,805)                          | (141,153)      |
| Net cash flows used in investing activities             | (62,421)                           | (24)           |
| Net cash flows provided by financing activities         | 659,321                            | 8,847          |
| Foreign exchange differences                            | (6,802)                            | 5,052          |
| Cash and cash equivalents at the beginning of the year  | 340,450                            | 467,728        |
| <b>Cash and cash equivalents at the end of the year</b> | <b>771,743</b>                     | <b>340,450</b> |

### *Net Cash Flows Provided By/Used In Operating Activities*

Net cash used in operating activities increased by \$17.7 million from \$141.2 million in 2023 to \$158.8 million in 2024. This change was primarily due to an increase in operating expenditures, the underlying reasons for which are described above, partially offset by an increase in the amount of cash received related to the achievement of clinical development milestones in the current period as compared to the same period in the prior year.

### *Net Cash Flows Provided By/Used In Investing Activities*

Net cash flows used in investing activities increased by \$62.4 million from \$0.0 million in 2023 to \$62.4 million in 2024. This change was primarily due to investments in marketable securities.

### *Net Cash Flows Provided By Financing Activities*

Net cash flows provided by financing activities was \$659.3 million in 2024 compared to \$8.9 million in 2023, an increase of \$650.5 million. This change was primarily related to the February 2024 Offering and the December 2024 Offering, which together generated net proceeds of \$645.0 million after deducting underwriting discounts and commissions and offering expenses paid by the Company. The remaining change is due to a \$5.1 million increase in the proceeds received from the exercise of Warrants and a \$0.5 increase in net proceeds from the exercise of options.

## 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, 2024 they are estimated to be a maximum of \$11.8 million due within one year and \$2.4 million due in more than a year. As of December 31, 2024, we had cash and cash equivalents of \$771.7 million which is sufficient to fund these obligations.

### *Leases*

We are party to a services agreement (the "Naarden Lease") pursuant to which an affiliate of Forbion leased us office space, the office lease agreement with Renaissance Aventura LLC, dated May 24, 2021, as amended April 9, 2024 (as amended, the "Miami Lease") and an office sublease agreement with GR8 People, Inc., dated April 2, 2024 (the "Yardley 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 \$75 thousand to \$82 thousand, increasing 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, 2027, unless terminated earlier by either party pursuant to the terms of the Miami Lease. Pursuant to the Yardley Lease, we are required to pay annual rent ranging from \$189 thousand to \$194 thousand, increasing from the low end of the range to the higher end of the range for each year of the lease. The Yardley Lease will expire by its terms on April 3, 2026, unless terminated earlier by either party pursuant to the terms of the Yardley Lease.

### *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 "*Business—Marketing and Sales*" above for a description of the Menarini License.

## **2.6 MATERIAL SUBSEQUENT EVENTS**

See Note 24 (*Events After the Reporting Period*) to the Consolidated Financial Statements included in chapter 8.1 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-commercial, 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 1A. Risk Factors*” in our annual report on Form 10-K filed with the Securities and Exchange Commission on February 26, 2025.

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 expressed 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 | <p>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.</p> <p>The regulatory approval process of the FDA, the EMA, the MHRA, and comparable regulatory authorities are lengthy, time-consuming and inherently</p> | <p>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. Therefore, the</p> | <p>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.</p> <p>Although the Company monitors the regulatory landscape and engages with the</p> |

|                        |                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                           |
|------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                        | <p>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.</p> | <p>ultimate impact on the financial position, cash flows and results of operations cannot be quantified. 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.</p> <p>Failure to comply with regulatory 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.</p> | <p>authorities when it deems that necessary, this is an inherent risk in biotech drug development and therefore has limited mitigation and improvement abilities.</p>                                                                     |
| Dependence on Menarini | <p>The Company relies on its collaboration with Menarini for the commercialization of the product in certain European areas.</p>                                                                        | <p>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. Because obicetrapib is not yet approved, we cannot quantify the impacts of these risks on the Company's financial position, cash flows, and</p>                                                                                      | <p>Together with Menarini, the Company has created a governance structure involving significant collaboration and oversight and in which all activities are monitored and discussed on a regular basis, including at the Board level.</p> |

|                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | results of operations.                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|---------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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. The precise impact of this risk on the Company's financial position, cash flows, and results of operations is uncertain. | <p>We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, and contractors.</p> <p>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 through for example, implementing additional training and testing as well as enhanced policies and controls around data security.</p> |
| 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. Because we have no control over competitors' activities, we cannot quantify the impacts of these risks on the Company's financial position, cash flows, and                                                                                        | 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.                                                                                                                                                                                                                   |

|                                       |                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                   |
|---------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                       |                                                                                                                                                                                                                                                                                                             | results of operations.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                   |
| 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. Because obicetrapib is not yet approved, we cannot quantify the impacts of these risks on the Company's financial position, cash flows, and results of operations. | 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 obicetrapib. If these third parties or consultants do not successfully carry out their contractual duties or meet | If the Company's CROs, CMOs or any other third parties upon which the Company relies on for administration and conduct of its clinical trials do not successfully carry out their contractual                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | The Company reviews and monitors the activities of third parties. These include setting contractual deliverables, quality assurance audits and performance reports, among other activities.                       |

|               |                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                              |
|---------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|               | <p>expected deadlines, the Company may be unable to obtain regulatory approval for or commercialize obicetrapib, if approved.</p>                                                                                                                                                                                                                     | <p>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. The precise impact of this risk on the Company's financial position, cash flows, and results of operations is uncertain.</p> |                                                                                                                                                                                                                                                                                                                              |
| Capital needs | <p>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.</p> | <p>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</p>                                                                                                                                                                                                                                                                                                                                                                             | <p>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. The Company has also implemented and maintains an "at-the-market" offering program under which it may raise relatively</p> |

|                                                      |                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                           |
|------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                      |                                                                                                                                                                                                                                                                                                                                                                                                          | precise impact of this risk on the Company's financial position, cash flows, and results of operations is uncertain.                                                                                                                                                                                           | small amounts of capital from time to time as needs arise.                                                                                                                                                                |
| Financial position                                   | The Company's ability to use its tax losses to offset future taxable income may be subject to certain limitations.                                                                                                                                                                                                                                                                                       | The Company's ability to utilize tax losses and tax loss 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.                  | The Company continuously monitors changes in tax laws to 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 and Israel-Hamas War | 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. On 7 October 2023, the Israel-Hamas War escalated. | Uncertainty and instability resulting from the conflict between Russia and Ukraine and Israel Hamas War could negatively impact our business operations and disrupt our supply chain. The precise impact of this risk on the Company's financial position, cash flows, and results of operations is uncertain. | The Company continues to monitor the situation to be able to take action if needed.                                                                                                                                       |
| Outbreaks and other global health crises             | The COVID-19 pandemic has impacted worldwide economic activity and future global health crises may pose similar risks and adversely affect our business and that of our suppliers, CROs, CMOs 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 global health crises may result in reduced operations, delays in the start of                                                                           | The Company together with its partners have put into place actions, such as conducting our Phase 3 clinical trial study visits virtually rather than physically, to minimize the impact from future global health crises. |

|  |  |                                                                                                                                                                                                                                                                                                                                                                                          |  |
|--|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|  |  | clinical trials or other research and development efforts, business disruption for the Company and its suppliers, CROs, CMOs and other third parties with which the Company does business, and potential delays or disruptions related to regulatory approvals. The precise impact of this risk on the Company's financial position, cash flows, and results of operations is uncertain. |  |
|--|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|

The above risks have not materialized during the period ended on December 31, 2024. 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 13 to the consolidated financial statements as well as section "Item 1A. Risk Factors" in the Company's Form 10-K filed with the SEC for the year ended December 31, 2024.

#### 4 CONTROLS AND PROCEDURES

The company has implemented a Risk & Control framework, based on the COSO 2013 internal control framework, for enhancing the control environment as well as compliance with the U.S. SEC's Sarbanes Oxley (SOX) Act of 2002, which is a requirement for a company listed on the NASDAQ. As part of the SOX implementation program, the company's Risk & Control framework was further improved in 2024, focusing on business process, IT and entity level controls. Improvement of the Risk & Control framework is an ongoing effort of the Company. More information around the SOX implementation program is disclosed in the Company's Form 10-K filed with the SEC for the year ended December 31, 2024.

#### 5 CORPORATE GOVERNANCE

##### 5.1 Dutch Corporate Governance Code

For the fiscal year to which this report relates, the Dutch Corporate Governance Code updated in 2022 (the "DCGC") has been applied. The text of the DCGC can be accessed at <http://www.mccg.nl>.

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.

*Internal audit function (best practice provisions 1.3.1, 1.3.2, 1.3.3, 1.3.4, 1.3.5 and 1.3.6)*

The Company has not established an internal audit department, considering its size of organization. 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, 5.1.1, 5.1.3)*

The composition of our Board and its Nomination and Corporate Governance Committees currently is now compliant with the DCGC, as more than half of the members of the Board and its Nomination and Corporate Governance Committee 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 fully comply with this best practice provision, and will continuously evaluate its ability to appoint new independent board members to the Board, which the Company has done recently by appointing an independent Chairman at the 2024 General Meeting and by appointing new directors at the next General meeting.

*Compensation (best practice provisions 3.1.2, 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 equal to 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.

## **5.2 Code of business conduct and ethics and other corporate governance practices**

We have a code of business conduct and ethics which outlines the principles of legal and ethical business conduct under which we will do business. The code of business conduct and ethics includes a provision that provides for a process by which employees and directors can report potential irregularities. The code of business conduct and ethics also provides protection from retaliation or discrimination by the Company against whistleblowers due to reporting issues relating to compliance with applicable laws and regulations. This code applies to all of our employees, officers and directors. Our code of business conduct and ethics is available on our website at <https://ir.newamsterdampharma.com/corporate-governance/governance-overview>. Our website and its contents are not incorporated into this annual report.

The adoption of our code of business conduct and ethics applies to all directors, officers and employees of NewAmsterdam Pharma Company 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.

## 5.3 General Meeting

### 5.3.1 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.

### 5.3.2 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.

### **5.3.3 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 5.3.1). 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.

## **5.4 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, 2024, 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. (68)*        | M               | American    | 21-11-2022                  | 2025                                 | 100%                                     |
| John Kastelein, M.D. (71)**         | M               | Dutch       | 21-11-2022                  | 2027                                 | 100%                                     |
| James N. Topper, M.D., Ph.D. (63)** | M               | American    | 21-11-2022                  | 2025                                 | 80%                                      |
| Louis Lange, M.D., Ph.D. (76)**     | M               | American    | 21-11-2022                  | 2028                                 | 100%                                     |
| Nicholas Downing, M.D. (40)**       | M               | American    | 21-11-2022                  | 2027                                 | 100%                                     |
| John W. Smither (71)**              | M               | American    | 14-01-2023                  | 2026                                 | 100%                                     |
| Janneke van der Kamp (49)**         | F               | Dutch       | 01-04-2023                  | 2026                                 | 100%                                     |
| William H. Lewis J.D., M.B.A(56)**  | M               | American    | 04-01-2024                  | 2028                                 | 100%                                     |
| Mark McKenna(45)**                  | M               | American    | 16-07-2024                  | N/A                                  | 75%                                      |
| Wouter Joustra(36)**                | M               | Dutch       | 16-07-2024                  | N/A                                  | 100%                                     |

\* Executive director

\*\* Non-executive director

Mark C. McKenna and Wouter Joustra were appointed by the Board of Directors as temporary non-executive directors on July 16, 2024 to fulfill vacant positions within the Board of Directors until their formal appointment at the next annual General Meeting.

Adele Gulfo was appointed by the Board of Directors as temporary non-executive director on April 15, 2025 to fulfill a vacant position within the Board of Directors until her proposed appointment by the General Meeting at the next annual General Meeting. Adele Gulfo has served as a member of the Board of Directors since April 2025.

### ***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 of Directors.

### ***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 of Directors.

*Dr. James N. Topper.* James N. Topper, M.D., Ph.D., was appointed to the Board of Directors in November 2022. Dr. Topper previously served as Frazier Lifescience Corporation's ("FLAC") 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 Inovaviva), 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 of Directors.

*Dr. Louis Lange.* Louis Lange, M.D., Ph.D., was appointed to the Board of Directors 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 of Directors.

*Dr. Nicholas Downing.* Nicholas Downing, M.D., was appointed to the Board of Directors 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 of Directors.

*John W. Smither.* John Smither has served as a member of the Board of Directors since January 2023. Mr. Smither previously served as the Chief Financial Officer of Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) from May 2019 until March 2021, and again as Interim Chief Financial Officer from September 2023 to the present, 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 presently serves on the board of directors of Genelux serving as chair of its compensation committee and as a member of its audit committee. Mr. Smither also served on the board of directors and audit committee chair of eFFECTOR Therapeutics, Inc. (Nasdaq: EFTR) from March 2018 to September 2023 and Applied Molecular Transport, Inc. (Nasdaq: AMTI) from January 2022 to December 2023. Mr. Smither also served as a member of the nomination and corporate governance committee of eFFECTOR Therapeutics and the compensation committee of Applied Molecular Transport. Mr. Smither previously served on the board of directors of Achaogen, Inc. and Principia Biopharma Inc and as the chair of their audit committees. 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 of Directors.

*Janneke van der Kamp.* Janneke van der Kamp joined the Board of Directors in April 2023. 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 of Directors.

*William H. Lewis, J.D., M.B.A.* William H. Lewis has served as a member of the Board of Directors and Chair since January 2024. Mr. Lewis was appointed as temporary non-executive director in fulfilment of a vacant position within the Board of Directors until his proposed appointment by the General Meeting at the next annual General Meeting. Mr. Lewis has more than 30 years of executive experience in the pharmaceutical and finance industries both in the U.S. and internationally. Mr. Lewis has served as President, Chief Executive Officer and director at Insméd Incorporated ("Insméd") since 2012 and has served as Chair of Insméd's board of directors since November 2018. Prior to joining Insméd in 2012, Mr. Lewis served as Co-Founder, President, and Chief Financial Officer of Aegerion Pharmaceuticals, Inc. from 2005 until 2011. Prior to Mr. Lewis' time at Aegerion, he spent approximately 10 years working in investment banking in the U.S. and Europe. He also previously worked for the U.S. government. Mr. Lewis holds a J.D. with Honors and an M.B.A., both from Case Western Reserve University, and a B.A., *cum laude*, from Oberlin College. He is a member of the Board of Trustees of Case Western Reserve University and of BioNJ, the life sciences association for New Jersey.

We believe that Mr. Lewis' significant experience as a public company executive in the life sciences industry and his other professional experience in the finance industry provide him the qualifications and skills to serve on the Board of Directors.

*Mark C. McKenna.* Mark C. McKenna has served as a member of the Board of Directors since July 2024. Mr. McKenna is the founder, Chairman and Chief Executive Officer of Mirador Therapeutics, and currently serves as Chairman of the board of directors of Apogee Therapeutics, Inc. (Nasdaq: APGE) and a director at Spyre Therapeutics, Inc. (Nasdaq: SYRE). In addition, Mr. McKenna serves as a venture partner at Arch Venture Partners and Senior Advisor at Fairmount Funds. Previously, Mr. McKenna was President, Chief Executive Officer and Chairman of the Board of Directors of Prometheus Biosciences, Inc., which was acquired by Merck & Co, Inc. in June 2023. Earlier, Mr. McKenna was a corporate officer of Bausch Health and served as President of its subsidiary, Salix Pharmaceuticals, Inc. Prior to Salix Pharmaceuticals, Mr. McKenna spent more than a decade in various roles with Bausch + Lomb, also a division of Bausch Health, most recently as Senior Vice President and General Manager of its U.S. Vision Care business. Mr. McKenna was Ernst & Young's Entrepreneur of the Year in 2023 and holds a B.S. in marketing from Arizona State University and an M.B.A. from Azusa Pacific University.

We believe that Mr. McKenna's significant experience as a public company executive in the life sciences industry and his other professional experiences provide him the qualifications and skills to serve on the Board of Directors.

*Wouter Joustra.* Wouter Joustra has served as a member of the Board of Directors since July 2024. Mr. Joustra currently serves as a General Partner at Forbion, a leading global life sciences venture capital firm with deep expertise in Europe, where his responsibilities include deal origination, general portfolio management and divestment strategies. Prior to joining Forbion in 2019, Mr. Joustra was a Senior Trader and Executive Board member of the life sciences franchise at Kempen, a European boutique investment bank, where he was responsible for managing Kempen's trading portfolio and was involved in deal structuring, equity capital markets transactions, and larger block trades. Mr. Joustra currently serves on the board of directors of VectorY Therapeutics, Beacon Therapeutics, EnGene Holdings Inc. (Nasdaq: ENGN), Navigator Medicines and Verdiva Bio. Mr. Joustra previously served as a member of the board of directors of several companies, including Gyroscope Therapeutics Holdings plc until the closing of its acquisition by Novartis AG in February 2022, VectivBio AG (Nasdaq: VECT) from December 2022 until the closing of its acquisition by Ironwood Pharmaceuticals, Inc. in December 2023, Aiolos Bio, Inc. until the closing of its acquisition by GSK plc in February 2024 and Forbion European Acquisition Corporation, a special purpose acquisition company, until its completion of the business combination with EnGene Holdings Inc. in October 2023. Mr. Joustra holds an M.Sc. in Business Administration and a B.Sc. in International Business and Management from the University of Groningen.

We believe that Mr. Joustra's board experience and significant experience as an investor in the life sciences industry provide him the qualifications and skills to serve on the Board of Directors.

*Adele Gulfo.* Ms Gulfo most recently served as Chief Executive Officer, Biopharma Commercial at Sumitomo Pharma America, Inc., where she led the organization to 46% revenue growth and delivered significant profit improvement across a diverse portfolio spanning oncology, rare disease, urology, neurology, and women's health. Previously, she was Chief Commercial and Business Development Officer at Sumitovant Biopharma (2020-2023) until its integration into Sumitomo Pharma America. Prior to that, she served as Chief Commercial Development Officer at Roivant Sciences, where she played a key role in the formation of Sumitovant and was instrumental in the launch preparations and commercialization of several key brands, including ORGOVYX (prostate cancer), GEMTESA

(overactive bladder), RETHYMIC (congenital athymia), and MYFEMBREE (women's health). Earlier in her career, Ms. Gulfo held several senior leadership roles at Pfizer, including President and General Manager of the company's \$12B+ US Primary Care Business Unit and Country Manager for its U.S Biopharma Business, where she oversaw Market Access and Commercial Operations across the Primary Care, Speciality, and Oncology divisions. Earlier in her career at Pfizer, she was instrumental in the development, launch, and commercial success of LIPITOR, which became the world's best-selling medicine. Before joining Pfizer, Ms. Gulfo help multiple Vice President positions at AstraZeneca, including leadership of Commercial Readiness, Business Development, and the Cardiovascular Business Unit, where she successfully led the launch and growth of Crestor into a multi-billion-dollar brand.

We believe that Ms. Gulfo's board experience and significant experience as an investor in the life sciences industry provide her the qualifications and skills to serve on the Board of Directors.

Louis Lange, John W. Smither, Janneke van der Kamp, Nicholas Downing, William H. Lewis, Mark C. McKenna and Adele Gulfo are independent within the meaning of the DCGC.

## 5.5 Committees

### 5.5.1 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, 2024, the committees were composed as follows:

|                               | <b>Audit committee</b> | <b>Compensation committee</b> | <b>Nomination and corporate governance committee</b> | <b>Attendance Rate</b> |
|-------------------------------|------------------------|-------------------------------|------------------------------------------------------|------------------------|
| Louis Lange, M.D., Ph.D.      |                        | X*                            | X                                                    | 100%                   |
| John W. Smither               | X*                     |                               |                                                      | 100%                   |
| Nicholas Downing, M.D.        |                        |                               | X                                                    | 100%                   |
| Janneke van der Kamp          |                        |                               | X                                                    | 100%                   |
| William H. Lewis J.D., M.B.A* | X                      | X                             | X*                                                   | 100%                   |
| Mark McKenna                  | X                      | X                             |                                                      | 75%                    |

\* Chairperson

### 5.5.2 Audit committee

The responsibilities of our audit committee include:

- 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 Company's audit plan with the Company's internal audit function and the Dutch independent auditor;
- d. reviewing and discussing the essence of the audit results with the Company's internal audit function;
- e. reviewing and discussing certain matters with the Dutch independent auditor;
- f. 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;
- g. reviewing and discussing the effectiveness of the design and operation of the Company's risk management and control systems;
- h. 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
- i. 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 four times. The main topics discussed included cybersecurity, cash management, internal controls, press releases and the filing of the Company's annual and interim condensed financial statements with the SEC and the filing of the Company's statutory accounts.

### **5.5.3 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. The main topics discussed included newly hired staff, the Company's equity plans, salary changes, and bonus approvals.

### **5.5.4 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 met once. The meeting was held to discuss the appointment of Janneke van der Kamp to the Board.

## **5.6 Diversity**

The Company is working on a diversity and inclusion policy with respect to the composition of the Board, and the Company's senior management (as defined by that policy). The Company supports, values, fosters, cultivates and preserves a culture of diversity and inclusion. In this respect, diversity refers to the different characteristics that make individuals unique, such as age, gender, race, ethnicity, sexual orientation, physical abilities, religious beliefs, socio-economic background, experiences, qualifications, knowledge and abilities. The Company's diversity and inclusion initiatives, ambitions and objectives apply, without limitation, to its practices and policies on recruitment, selection and retention, compensation and benefits, professional development and training, social and recreational programs. The Company is committed to the ongoing development of a safe working environment throughout the Company that is free from harassment and discrimination against any individual on the basis of their unique characteristics.

## **6 COMPENSATION**

### **6.1 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.

## **6.2 Compensation of directors**

See Note 21 (*Related Parties*) to the Consolidated Financial Statements included in chapter 8.1 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.

## **6.3 Pay ratio**

The DCGC recommends that the Company provides 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, 2024. 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 2.38 compared to 1 to 1.75 as at December 2023 (rounded to the nearest integer).

## **7 PROTECTIVE MEASURES**

Under Dutch law, various protective measures are possible and permissible within the boundaries set by Dutch law and Dutch case law.

In this respect, certain provisions of the Articles of Association may make it more difficult for a third-party to acquire control of us or effect a change in the composition of the Board. These include:

- a provision that the Company's directors can only be appointed on the basis of a binding nomination prepared by the Board which can only be overruled by a two-thirds majority of votes cast representing more than half of our issued share capital;
- a provision that the Company's directors can only be dismissed by the General Meeting by a two-thirds majority of votes cast representing more than half of our issued share capital, unless the dismissal is proposed by the Board in which latter case a simple majority of the votes cast would be sufficient;
- a provision allowing, among other matters, the former chairperson of the Board or the Company's former Chief Executive Officer to manage the Company's affairs if all of its directors are dismissed and to appoint others to be charged with our affairs, including the preparation of a binding nomination for our directors as discussed above, until new directors are appointed by the General Meeting on the basis of such binding nomination; and
- a requirement that certain matters, including an amendment of the Articles of Association, may only be resolved upon by the General Meeting if proposed by the Board.

Dutch law also allows for, and we have adopted, staggered multi-year terms of our directors, as a result of which only part of the Board will be subject to appointment or re-appointment in any given year.

Furthermore, in accordance with the DCGC, shareholders who have the right to put an item on the agenda for the General Meeting or to request the convening of a General Meeting shall not exercise such rights until after they have consulted the Board. If exercising such rights may result in a change in our strategy (for example, through the dismissal of one or more directors), the Board must be given the opportunity to invoke a reasonable period of up to 180 days to respond to the shareholders' intentions. If invoked, the 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, the Board shall report on this consultation and the exploration of alternatives to the 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 or a statutory cooling-off period (as discussed below) has been previously invoked or (ii) in situations where a shareholder holds at least 75% of our issued share capital as a consequence of a successful public bid.

Moreover, the Board can invoke a cooling-off period of up to 250 days when shareholders, using their right to have items added to the agenda for a General Meeting or their right to request a General Meeting, propose an agenda item for the General Meeting to dismiss, suspend or appoint one or more directors (or to amend any provision in the Articles of Association dealing with those matters) or when a public offer for the Company is made or announced without our support, provided, in each case, that the Board believes that such proposal or offer materially conflicts with the interests of the Company and its business. During a cooling-off period, the General Meeting cannot dismiss, suspend or appoint directors (or amend the provisions in the Articles of Association dealing with those matters) except at the proposal of the Board. During a cooling-off period, the Board must gather all relevant information necessary for a careful decision-making process and at least consult with shareholders representing 3% or more of our issued share capital at the time the cooling-off period was invoked, as well as with our Dutch works council (if we or, under certain circumstances, any of our subsidiaries would have one). Formal statements expressed by these stakeholders during such consultations must be published on our website to the extent these stakeholders have approved that publication. Ultimately, one week following the last day of the cooling-off period, the 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. Shareholders representing at least 3% of our issued share capital may request the Enterprise Chamber (Ondernemingskamer) 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:

- the Board, in light of the circumstances at hand when the cooling-off period was invoked, could not reasonably have concluded that the relevant proposal or hostile offer constituted a material conflict with the interests of us and our business;
- the Board cannot reasonably believe that a continuation of the cooling-off period would contribute to careful policy-making; or
- other defensive measures, having the same purpose, nature and scope as the cooling-off period, have been activated during the cooling-off period and have not since been terminated or

suspended within a reasonable period at the relevant shareholders' request (i.e., no "stacking" of defensive measures).

## **8 FINANCIAL STATEMENTS**

### **8.1 Consolidated Financial Statements**

## CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND COMPREHENSIVE LOSS

|                                                            | <u>Note</u> | <u>For the year ended December 31,</u><br><u>2024</u> | <u>2023</u>      |
|------------------------------------------------------------|-------------|-------------------------------------------------------|------------------|
| <i>(In thousands of USD, except per share amounts)</i>     |             |                                                       |                  |
| Revenue                                                    | 4           | 45,563                                                | 14,090           |
| Operating expenses:                                        |             |                                                       |                  |
| Research and development expenses                          | 5           | (152,784)                                             | (160,347)        |
| Selling, general and administrative expenses               | 6           | (73,220)                                              | (38,381)         |
| Total operating expenses                                   |             | <u>(226,004)</u>                                      | <u>(198,728)</u> |
| Operating loss                                             |             | (180,441)                                             | (184,638)        |
| Other income (expense):                                    |             |                                                       |                  |
| Finance income                                             |             | 16,882                                                | 11,283           |
| Finance expense                                            | 20          | (26)                                                  | (6)              |
| Fair value change – earnout and warrants                   | 14          | (75,593)                                              | (10,284)         |
| Foreign exchange gains/(losses)                            | 13          | (6,598)                                               | 5,058            |
| Loss before tax                                            |             | (245,776)                                             | (178,587)        |
| Income tax expense                                         | 10          | 1                                                     | (27)             |
| Loss for the year                                          |             | (245,775)                                             | (178,614)        |
| Other comprehensive income (loss)                          |             |                                                       |                  |
| Foreign currency translation adjustments                   |             | —                                                     | —                |
| Unrealized gain on available-for-sale securities           | 16          | 45                                                    | —                |
| Income tax effects of other comprehensive income (loss)    |             | —                                                     | —                |
| Total comprehensive income (loss) for the year, net of tax |             | <u>(245,730)</u>                                      | <u>(178,614)</u> |
| Net loss per ordinary share                                | 19          |                                                       |                  |
| Basic and diluted                                          |             | \$ (2.60)                                             | \$ (2.17)        |

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

## CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

|                                                  |      | As at December 31, |                |
|--------------------------------------------------|------|--------------------|----------------|
|                                                  | Note | 2024               | 2023           |
| <i>(In thousands of USD)</i>                     |      |                    |                |
| <b>Assets</b>                                    |      |                    |                |
| <b>Non-current assets</b>                        |      |                    |                |
| Intangible assets                                | 12   | 88,698             | 88,698         |
| Property, plant and equipment, net               | 11   | 242                | 46             |
| Operating right of use asset                     | 11   | 431                | 55             |
| Long term prepaid expenses                       |      | —                  | 35             |
| <b>Total non-current assets</b>                  |      | <b>89,371</b>      | <b>88,834</b>  |
| <b>Current assets</b>                            |      |                    |                |
| Cash and cash equivalents                        | 15   | 771,743            | 340,450        |
| Marketable Securities                            | 16   | 62,447             | —              |
| Prepayments and other receivables                | 8    | 29,223             | 6,340          |
| <b>Total current assets</b>                      |      | <b>863,413</b>     | <b>346,790</b> |
| <b>Total assets</b>                              |      | <b>952,784</b>     | <b>435,624</b> |
| <b>Equity and liabilities</b>                    |      |                    |                |
| <b>Equity</b>                                    |      |                    |                |
| Share capital                                    | 17   | 13,444             | 10,173         |
| Share premium                                    | 17   | 1,318,165          | 641,210        |
| Other reserves                                   | 18   | 60,006             | 29,572         |
| Accumulated loss                                 |      | (553,759)          | (307,984)      |
| Unrealized gain on available-for-sale securities | 16   | 45                 | —              |
| Accumulated other comprehensive income (loss)    |      | 469                | 469            |
| <b>Total equity</b>                              |      | <b>838,370</b>     | <b>373,440</b> |
| <b>Non-current liabilities</b>                   |      |                    |                |
| Deferred revenue, net of current portion         | 4    | —                  | 1,019          |
| Lease liability, net of current portion          | 20   | 202                | —              |
| Derivative earnout liability                     | 14   | 44,799             | 7,788          |
| <b>Total non-current assets</b>                  |      | <b>45,001</b>      | <b>8,807</b>   |
| <b>Current liabilities</b>                       |      |                    |                |
| Accounts payable                                 |      | 4,744              | 16,923         |
| Accrued expenses and other current liabilities   | 9    | 20,901             | 14,878         |
| Deferred revenue, current                        | 4    | 6,008              | 8,942          |
| Lease liability, current                         | 20   | 246                | 60             |
| Derivative warrant liabilities                   | 14   | 37,514             | 12,574         |
| <b>Total current liabilities</b>                 |      | <b>69,413</b>      | <b>53,377</b>  |
| <b>Total equity and liabilities</b>              |      | <b>952,784</b>     | <b>435,624</b> |

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

## CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

|                                                                                          | Shareholders' Equity |                |               |                |                   |                            |                                    |                            |
|------------------------------------------------------------------------------------------|----------------------|----------------|---------------|----------------|-------------------|----------------------------|------------------------------------|----------------------------|
| (In thousands of USD)                                                                    | Note                 | Issued Capital | Share Premium | Other Reserves | Retained earnings | Other Comprehensive income | Cumulative Translation Adjustments | Total Shareholders' Equity |
| As at December 31, 2022                                                                  |                      | 10,055         | 630,608       | 5,028          | (129,370)         | —                          | 469                                | 516,790                    |
| Exercise of warrants                                                                     | 17                   | 97             | 10,116        | —              | —                 | —                          | —                                  | 10,213                     |
| Exercise of stock options                                                                | 17                   | 21             | 486           | (217)          | —                 | —                          | —                                  | 290                        |
| Share-based compensation                                                                 | 17                   | —              | —             | 24,761         | —                 | —                          | —                                  | 24,761                     |
| Total profit or loss and comprehensive loss for the year                                 |                      | —              | —             |                | (178,614)         | —                          | —                                  | (178,614)                  |
| As at December 31, 2023                                                                  |                      | 10,173         | 641,210       | 29,572         | (307,984)         | -                          | 469                                | 373,440                    |
| February 2024 Issuance of Ordinary Shares and Pre-Funded Warrants, net of issuance costs | 17                   | 759            | 189,206       | —              | —                 | —                          | —                                  | 189,965                    |
| December 2024 Issuance of Ordinary Shares and Pre-Funded Warrants, net of issuance costs | 17                   | 1,851          | 451,564       | —              | —                 | —                          | —                                  | 453,415                    |
| Exercise of Pre-Funded Warrants                                                          |                      | 279            | (279)         |                |                   | —                          |                                    |                            |
| Exercise of warrants                                                                     | 17                   | 168            | 27,673        | —              | —                 | —                          | —                                  | 27,841                     |
| Exercise of stock options                                                                | 17                   | 214            | 8,791         | (3,295)        | —                 | —                          | —                                  | 5,710                      |
| Share-based compensation                                                                 | 17                   | —              |               | 33,729         | —                 | —                          | —                                  | 33,729                     |
| Total loss and comprehensive loss for the period                                         |                      | —              | —             | —              | (245,775)         | 45                         | —                                  | (245,730)                  |
| As at December 31, 2024                                                                  |                      | 13,444         | 1,318,165     | 60,006         | -553,759          | 45                         | 469                                | 838,370                    |

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

## CONSOLIDATED STATEMENTS OF CASH FLOWS

|                                                                                     |           | For the year ended December 31, |                  |
|-------------------------------------------------------------------------------------|-----------|---------------------------------|------------------|
|                                                                                     | Note      | 2024                            | 2023             |
| <i>(In thousands of USD)</i>                                                        |           |                                 |                  |
| <b>Operating activities:</b>                                                        |           |                                 |                  |
| Loss for the year                                                                   |           | (245.775)                       | (178.614)        |
| <i>Non-cash adjustments to reconcile loss before tax to net cash flows:</i>         |           |                                 |                  |
| Depreciation and amortization                                                       | 11,20     | 236                             | 76               |
| Finance expense                                                                     | 20        | 12                              | 6                |
| Fair value change - derivative earnout and warrants                                 | 14        | 75.593                          | 10.284           |
| Foreign exchange (gains)/losses                                                     | 13        | 6.598                           | (5.058)          |
| Amortization of premium/discount on available-for-sale debt securities              |           | (227)                           |                  |
| Share-based compensation                                                            | 18        | 33.619                          | 24.572           |
| <i>Changes in working capital:</i>                                                  |           |                                 |                  |
| Changes in prepayments and other receivables                                        |           | (17.459)                        | 4.031            |
| Changes in trade and other payables                                                 |           | (7.449)                         | 12.255           |
| Changes in deferred revenue                                                         |           | (3.953)                         | (8.705)          |
| Interest paid                                                                       |           | —                               | —                |
| <b>Net cash (used in)/provided by operating activities</b>                          |           | <b>(158.805)</b>                | <b>(141.153)</b> |
| <b>Investing activities:</b>                                                        |           |                                 |                  |
| Purchase of equipment                                                               | 11        | (245)                           | (24)             |
| Purchase of available-for-sale debt securities                                      | 16        | (62.176)                        |                  |
| <b>Net cash used in investing activities</b>                                        |           | <b>(62.421)</b>                 | <b>(24)</b>      |
| <b>Financing activities:</b>                                                        |           |                                 |                  |
| Proceeds from February 2024 offering of Ordinary Shares and Pre-Funded Warrants     | 17        | 190.481                         | —                |
| Transaction costs on February 2024 issue of Ordinary Shares and Pre-Funded Warrants | 17        | (515)                           | —                |
| Proceeds from December 2024 offering of Ordinary Shares and Pre-Funded Warrants     | 17        | 455.026                         | —                |
| Transaction costs on December 2024 issue of Ordinary Shares and Pre-Funded Warrants | 17        | (25)                            | —                |
| Proceeds from exercise of warrants                                                  | 17        | 13.761                          | 8.622            |
| Proceeds from exercise of options                                                   | 17        | 1.768                           | 290              |
| Payment of withholding taxes related to net share settlement of exercised options   | 17        | (989)                           | —                |
| Payment of lease liabilities                                                        | 20        | (186)                           | (65)             |
| <b>Net cash provided by financing activities</b>                                    |           | <b>659.321</b>                  | <b>8.847</b>     |
| Net change in cash and cash equivalents                                             |           | 438.095                         | (132.330)        |
| Foreign exchange differences                                                        |           | (6.802)                         | 5.052            |
| Cash and cash equivalents at the beginning of the year                              |           | 340.450                         | 467.728          |
| <b>Cash and cash equivalents at the end of the year</b>                             | <b>15</b> | <b>771.743</b>                  | <b>340.450</b>   |

*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. (“NewAmsterdam Pharma” or the “Company”) is a late-stage biopharmaceutical company whose mission is to improve patient care in populations with metabolic diseases where currently approved therapies have not been adequate or well-tolerated. 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 Company’s ordinary shares, nominal value \$0.12 per share (the “Ordinary Shares”) are listed on the Nasdaq Global Market and trade under the symbol “NAMS.”

In November 2022, the Company conducted an internal reorganization for the purpose of participating in the merger of the acquired company, Frazier Lifesciences Acquisition Corporation. As a result of the internal restructuring and merger, NewAmsterdam Pharma Holding B.V., FLAC and NewAmsterdam Pharma Investment Corporation, a new Cayman-based exempted company, became wholly-owned subsidiaries of the Company.

The Company is subject to risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including, but not limited to, development by competitors of more advanced or effective therapies, dependence on key executives, protection of and dependence on intellectual property, compliance with government regulations and ability to secure additional capital to fund operations. Significant additional research and development efforts and regulatory approval will be required prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

The consolidated financial statements were authorized by the Company’s Board of Directors (the “**Board**”) for issuance on April 25, 2025.

#### *Group Information*

In November 2022, the Company became the ultimate parent company of the Group after an internal reorganization, as previously mentioned.

As per December 31, 2024, the consolidated financial statements of the Group include:

| <b>Name</b>                                           | <b>Legal seat</b>        | <b>Country of<br/>incorporation</b> | <b>Percent<br/>equity<br/>interest<br/>2024</b> | <b>Percent<br/>equity<br/>interest<br/>2023</b> |
|-------------------------------------------------------|--------------------------|-------------------------------------|-------------------------------------------------|-------------------------------------------------|
| 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.

## **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.

Since NewAmsterdam Pharma Company N.V.’s statement of profit or loss and comprehensive loss for 2024 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.

### ***Functional and Presentation Currency***

IAS 21 (revised) defines the functional currency as the currency of the primary economic environment in which an entity operates.

The functional currency of the Company and its subsidiaries is the United States Dollar (“USD” or “\$”). The consolidated financial statements are presented in US Dollar (“USD” or “\$”). In these notes, US Dollar amounts are presented in thousands, except for share and per share amounts and as otherwise indicated.

### ***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 Company has incurred net operating losses and negative cash flows from operations since its inception and had an accumulated deficit of \$553.8 million as of December 31, 2024. Management has assessed it appropriate to prepare these consolidated financial statements on a going concern basis, taking into account the Company's cash and cash equivalents balance of \$771.7 million as of December 31, 2024. Management believes that the existing financial resources are sufficient to continue operating activities, and 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 at least the twelve-month period 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. 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.

### ***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:

|                                | Estimated Useful Life (in years) | Depreciation Rate |
|--------------------------------|----------------------------------|-------------------|
| Computer equipment             | 5                                | 20%               |
| Office furniture and equipment | 5                                | 20%               |
| Furniture and Fixtures         | 5                                | 20%               |

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.

### ***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 12 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**”). 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 14. 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 and cash equivalents***

Cash comprises checking and savings deposits. The carrying amount of these assets is approximately equal to their fair value due to their short-term nature. The Company maintains certain deposits which exceed the amounts covered by insurance provided by the government of the country in which the deposits are held. The Company has not experienced any losses related to amounts held in excess of such limits.

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents.

### ***Marketable Securities***

Marketable securities consist of investments in U.S. government and U.S. government agency obligations that are classified as available-for-sale. All marketable securities have a maturity of less than one year from the date of purchase. Further, since these securities are highly liquid and available to fund current operations, they are classified as current assets on the consolidated balance sheets.

The Company adjusts the cost of available-for-sale debt securities for amortization of premiums and accretion of discounts to maturity. The Company includes such amortization and accretion as a component of interest income, net based on the effective interest method. Realized gains and losses and declines in value, if any, that the Company judges to be the result of impairment or as a result of recognizing an allowance for credit losses on available-for-sale securities are reported as a component of interest income, net. To determine whether an impairment exists, the Company considers whether it intends to sell the debt security and, if the Company does not intend to sell the debt security, it considers available evidence to assess whether it is more likely than not that it will be required to sell the security before the recovery of its amortized cost basis. During the year ended December 31, 2024 the Company determined it did not have any securities that were other-than-temporarily impaired. Prior to 2024 the Company held no marketable securities.

Marketable securities are measured at fair value through other comprehensive income, excluding accrued interest, with their unrealized gains and losses included as a component of accumulated other comprehensive income or loss, which is a separate component of stockholders' equity. During the years ended December 31, 2024 and 2023, the Company did not have any realized gains or losses on marketable securities.

## ***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 20 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.

### ***Foreign Currency and Currency Translation***

Monetary assets and liabilities denominated in currencies other than the functional currency are remeasured into the functional currency at exchange rates prevailing at the balance sheet dates. Non-monetary assets and liabilities denominated in foreign currencies are remeasured into the functional currency at the exchange rates prevailing at the date of the transaction. Exchange gains or losses arising from foreign currency transactions are included in the determination of net loss for the respective periods.

Prior to January 1, 2023 the functional currency of the Company and its subsidiaries was the Euro. The presentation currency of the Company is USD. The Company translated assets and liabilities in prior periods at the exchange rate in effect on the balance sheet date. Revenues and expenses are translated at the exchange rate prevailing at the date of the transaction. Unrealized translation gains and losses are recorded as cumulative translation adjustments which are included in the Company's balance sheet within accumulated other comprehensive income (loss).

### ***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, 2024 did not have any material impact on the Company's consolidated financial statements.

### **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.

This does not currently impact the Company as it does not have equity instruments used to settle a liability.

#### **Amendments to IAS 1 — Presentation of Financial Statements — Non-current Liabilities with Covenants (Effective January 1, 2024)**

Published in November 2022, the amendments specify that only covenants that an entity is required to comply with on or before the end of the reporting period affect the entity's right to defer settlement of a liability for at least twelve months after the reporting date and therefore must be considered in assessing the classification of the liability as current or non-current. Such covenants affect whether the right exists at the end of the reporting period, even if compliance with the covenant is assessed only after the reporting date (e.g. a covenant based on the entity's financial position at the reporting date that is assessed for compliance only after the reporting date).

The IASB also specifies that the right to defer settlement of a liability for at least twelve months after the reporting date is not affected if an entity only has to comply with a covenant after the reporting period. However, if the entity's right to defer settlement of a liability is subject to the entity complying with covenants within twelve months after the reporting period, an entity discloses information that enables users of financial statements to understand the risk of the liabilities becoming repayable within twelve months after the reporting period. This would include information about the covenants (including the nature of the covenants and when the entity is required to comply with them), the carrying amount of related liabilities and facts and circumstances, if any, that indicate that the entity may have difficulties complying with the covenants.

This does not currently impact the Company as it does not have any non-current liabilities with covenants.

#### **Amendments to IAS 7 Statement of Cash Flows and IFRS 7 Financial Instruments: Disclosures – Supplier Finance Arrangements (Effective January 1, 2024)**

The International Accounting Standards Board (IASB) has published 'Supplier Finance Arrangements (Amendments to IAS 7 and IFRS 7)' to add disclosure requirements, and 'signposts' within existing disclosure requirements, that ask entities to provide qualitative and quantitative information about supplier finance arrangements.

The amendments introduce two new disclosure objectives – one in IAS 7 and another in IFRS 7 – for a company to provide information about its supplier finance arrangements that would enable users (investors) to assess the effects of these arrangements on the company's liabilities and cash flows, and the company's exposure to liquidity risk. Companies also need to disclose the type and effect of non-

cash changes in the carrying amounts of the financial liabilities that are part of a supplier finance arrangement.

The IASB's amendments apply to supplier finance arrangements that have all of the following characteristics.

- A finance provider pays amounts a company (the buyer) owes its suppliers.
- A company agrees to pay under the terms and conditions of the arrangements on the same date or at a later date than its suppliers are paid.
- The company is provided with extended payment terms or suppliers benefit from early payment terms, compared with the related invoice payment due date.

The amendments do not apply to arrangements for financing receivables or inventory.

Key changes or amendments in Supplier Finance Arrangements include:

- The amendments not define supplier finance arrangements but describe the characteristics of an arrangement for which an entity is required to provide the information. The amendments note that arrangements that are solely credit enhancements for the entity or instruments used by the entity to settle directly with a supplier the amounts owed are not supplier finance arrangements.
- Entities will have to disclose in the notes information that enables users of financial statements
  - to assess how supplier finance arrangements affect an entity's liabilities and cash flows and to understand the effect of supplier finance arrangements on an entity's
  - exposure to liquidity risk and how the entity might be affected if the arrangements were no longer available to it.
- Complement current requirements in IFRSs by adding to IAS 7 additional disclosure requirements about:
  - the terms and conditions of the supplier finance arrangements;
  - for the arrangements, as at the beginning and end of the reporting period:
    - a) the carrying amounts of financial liabilities that are part of the arrangement and the associated line item presented;
    - b) the carrying amount of financial liabilities disclosed under a) for which suppliers have already received payment from the finance providers;
    - c) the range of payment due dates (for example, 30 to 40 days after the invoice date) of financial liabilities disclosed under a) and comparable trade payables that are not part of a supplier finance arrangement; and
  - the type and effect of non-cash changes in the carrying amounts of the financial liabilities that are part of the arrangement.

The IASB decided that, in most cases, aggregated information about an entity's supplier finance arrangements will satisfy the information needs of users of financial statements.

### **Amendments to IFRS 16 *Leases* – Lease Liability in a Sale and Leaseback (Applies retrospectively from 1 January 2024)**

Amendments to IFRS 16 *Leases* impact how a seller-lessee accounts for variable lease payments that arise in a sale-and-leaseback transaction. The variable lease payments are recognized as a liability.

The amendments confirm the following.

- On initial recognition, the seller-lessee includes variable lease payments when it measures a lease liability arising from a sale-and-leaseback transaction.
- After initial recognition, the seller-lessee applies the general requirements for subsequent accounting of the lease liability such that it recognizes no gain or loss relating to the right of use it retains.

A seller-lessee may adopt different approaches that satisfy the new requirements on subsequent measurement.

Under IAS 8 *Accounting Policies, Changes in Accounting Estimates and Errors*, a seller-lessee will need to apply the amendments retrospectively to sale-and-leaseback transactions entered into or after the date of initial application of IFRS 16.

### **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 21 *The Effects of Changes in Foreign Exchange Rates* - Lack of Exchangeability (Effective January 1, 2025)**

Under IAS 21 *The Effects of Changes in Foreign Exchange Rates*, a company uses a spot exchange rate when translating a foreign currency transaction. However, in rare cases, it is possible that one currency cannot be exchanged into another. This lack of exchangeability might arise when a government imposes controls on capital imports and exports, for example, or when it provides an official exchange rate but limits the volume of foreign currency transactions that can be undertaken at that rate. Consequently, market participants are unable to buy and sell currency to meet their needs at the official exchange rate and turn instead to unofficial, parallel markets.

Although few jurisdictions are affected by this, it can have a significant accounting impact for those companies affected.

Issued in August 2023, the International Accounting Standards Board (IASB) amended IAS 21 to clarify:

- when a currency is exchangeable into another currency; and
- how a company estimates a spot rate when a currency lacks exchangeability.

Under the amendments, companies will need to provide new disclosures to help users assess the impact of using an estimated exchange rate on the financial statements. These disclosures might include:

- the nature and financial impacts of the currency not being exchangeable;
- the spot exchange rate used;
- the estimation process; and
- risks to the company because the currency is not exchangeable.

**Amendments to IFRS 9 Financial Instruments and IFRS 7 Financial Instruments: Disclosures - Amendments to the Classification and Measurement of Financial Instruments (Effective January 1, 2026)**

The amendments include guidance on the classification of financial assets, including those with contingent features. Companies will now be required to provide additional disclosures on financial assets and financial liabilities that have certain contingent features including ESG-linked features.

The amendments also clarify when a financial asset or a financial liability is recognised and derecognised and to provide an exception for certain financial liabilities settled using an electronic payment system. The company generally derecognizes its trade payable on the settlement date however, the amendments provide an exception for the derecognition of financial liabilities. The exception allows the company to derecognize its trade payable before the settlement date when it uses an electronic payment system that meets all of the following criteria:

- no practical ability to withdraw, stop or cancel the payment instruction;
- no practical ability to access the cash to be used for settlement as a result of the payment instruction; and
- the settlement risk associated with the electronic payment system is insignificant.

**Amended by IFRS 18 Presentation and Disclosure in Financial Statements – (Effective January 1, 2027)**

Issued in April 2024, the amendments require all companies to use the operating profit subtotal as defined in IFRS 18 as the starting point for the indirect method of reporting cash flows from operating activities. Additionally, the presentation alternatives for cash flows related to interest and dividends paid and received will be removed and all income and expenses is to be classified into three new distinct categories based on a company's main business activities.

**IFRS 19 — Subsidiaries without Public Accountability: Disclosures (Effective January 1, 2027)**

Issued in May 2024, IFRS 19 specifies reduced disclosure requirements that an eligible entity is permitted to apply instead of the disclosure requirements in other IFRS Accounting Standards. This permits a subsidiary to provide reduced disclosures when applying IFRS Accounting Standards in its financial statements and focus more on user needs. A subsidiary that does not have public accountability, and has a parent that produces consolidated accounts under IFRS Accounting Standards, is permitted to apply IFRS 19.

Subsidiaries that currently apply the *IFRS for SMEs* Accounting Standard or local GAAP in their statutory financial statements will no longer need to prepare two sets of accounts for group reporting purposes if IFRS 19 is applied.

### **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 4, 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 5). 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 14.

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 14. 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 14.

### **Note 4 — Revenue**

On June 23, 2022, NewAmsterdam Pharma Holding B.V. 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 Company 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 Company 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 Company’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 Company and by the Company 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 do not currently 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 Company’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 research and development services are not highly interdependent or highly interrelated because the Company is able to fulfill its promise to transfer the licenses regardless of fulfilling its promise to perform the remaining research and development 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 intellectual property (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 \$120.9 million that was received by the Company in July 2022. The Company considers this non-refundable fee 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.

In 2022, at contract inception, the Company allocated \$98.6 million to the license performance obligation which was immediately recognized as revenue in its consolidated statement of operations and comprehensive loss and \$22.3 million to the R&D performance obligation, which is initially recognized as deferred revenue in the consolidated balance sheet. The revenue related to the R&D performance obligation is recognized over time as costs are incurred in connection with fulfilling the obligation. At each reporting date the Company reviews the total costs incurred to date and the total expected costs necessary to fulfill the R&D performance obligation. Revenue related to the R&D performance obligation is recognized based upon the percentage of total costs expected costs incurred to date based upon the latest information available to management.

The Menarini License also provides for certain milestone payments from Menarini to the Company upon the achievement of specified development, regulatory and commercial milestones linked to the enhanced value of the license performance obligation. More specifically, the Company 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 assessed the probability of significant reversals for any amounts that became likely to be realized prior to recognizing the variable consideration associated with these payments within the transaction price.

In the years ended December 31, 2024, 2023 and 2022 the Company recognized revenues of \$27.3 million, \$5.4 million and nil, respectively, related to the achievement of clinical milestones. Revenues related to the achievement of milestones under the Menarini License are attributed to the license performance obligation and are recognized when the milestone is achieved.

Additionally, in partial contribution to our costs of development of the Licensed Products, Menarini may pay us €27.5 million, payable in two equal annual installments. These development cost contributions are considered to be linked to the R&D performance obligation. Due to the scientific uncertainties around the commercialization of the Licensed Products based on the success of clinical trials, which is not within the control of the Company, the fixed €27.5 million is considered constrained at contract inception and is not initially recognized within the transaction price until it becomes highly probable of no significant revenue reversal.

In the year ended December 31, 2024, it was determined that the first installment of the development cost reimbursements was probable to be realized with no significant reversals. As such, the amount of the first installment was added to the transaction price. Based on the percentage of completion of the R&D performance obligation, as described above, \$11.9 million was recognized as revenue as a cumulative catchup and the remaining \$2.4 million was recognized as deferred revenue.

The deferred revenue is 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, the company recognizes as current liabilities the amount for which it expects to perform the associated services within twelve months after the reporting period and the remaining amounts are recognized as non-current liabilities.

Lastly, the Company 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.

To date the Menarini License has been the only source of revenue to the Company and all such revenues derive from Italy.

Revenue consisted of the following :

| <i>(In thousands of USD)</i>                                   | Year ended December 31, |               |
|----------------------------------------------------------------|-------------------------|---------------|
|                                                                | 2024                    | 2023          |
| License revenue attributed from license performance obligation | 27,325                  | 5,385         |
| License revenue attributed from R&D performance obligation     | 18,238                  | 8,705         |
| <b>Total revenue</b>                                           | <b>45,563</b>           | <b>14,090</b> |

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

| <i>(In thousands of USD)</i>                                    | 2024    | 2023    |
|-----------------------------------------------------------------|---------|---------|
| Beginning balance on January 1                                  | 9,960   | 18,665  |
| Addition of deferred revenue under the Menarini License         | 2,411   | —       |
| Revenue recognized under the Menarini License during the period | (6,365) | (8,705) |
| Ending balance on December 31                                   | 6,006   | 9,960   |

#### **Note 5 — Research and Development Expense**

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

|                                                | 2024             | 2023             |
|------------------------------------------------|------------------|------------------|
| Clinical expenses                              | (105,904)        | (106,770)        |
| Non-clinical expenses                          | (1,859)          | (2,917)          |
| Personnel expense (see Note 7)                 | (25,397)         | (21,799)         |
| Manufacturing costs                            | (17,188)         | (27,430)         |
| Regulatory expenses                            | (2,186)          | (1,297)          |
| Other R&D costs                                | (250)            | (134)            |
| <b>Total research and development expenses</b> | <b>(152,784)</b> | <b>(160,347)</b> |

#### **Note 6 — Selling, General and Administrative Expenses**

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

|                                                           | 2024            | 2023            |
|-----------------------------------------------------------|-----------------|-----------------|
| <b>Included in selling expenses:</b>                      |                 |                 |
| Commission expense                                        | (174)           | (281)           |
| <b>Included in general and administrative expenses:</b>   |                 |                 |
| Personnel expense (see Note 7)                            | (42,319)        | (17,267)        |
| Travel costs                                              | (2,025)         | (1,035)         |
| Intellectual property                                     | (2,403)         | (1,917)         |
| Legal costs                                               | (2,140)         | (2,168)         |
| Finance and administration                                | (3,421)         | (4,122)         |
| Transaction costs                                         | (596)           | (3,427)         |
| IT                                                        | (304)           | (111)           |
| Rent and office services                                  | (517)           | (227)           |
| Marketing and communication                               | (1,981)         | (793)           |
| Insurance                                                 | (1,815)         | (2,183)         |
| Depreciation and amortization                             | (236)           | (77)            |
| Commercial costs                                          | (12,880)        | (2,382)         |
| Business development                                      | (223)           | (745)           |
| Board fees                                                | (431)           | (336)           |
| Miscellaneous                                             | (194)           | (200)           |
| Filing fees                                               | (215)           | (313)           |
| Consulting fees                                           | (418)           | (176)           |
| Conferences                                               | (266)           | (136)           |
| Recruitment costs                                         | (662)           | (485)           |
| <b>Total selling, general and administrative expenses</b> | <b>(73,220)</b> | <b>(38,381)</b> |

### Note 7 — 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:

|                                                | 2024            | 2023            |
|------------------------------------------------|-----------------|-----------------|
| Wages, salaries and contracted personnel costs | (31,577)        | (13,589)        |
| Other employee benefits                        | (2,520)         | (905)           |
| Share based compensation expense               | (33,619)        | (24,572)        |
| <b>Total personnel expenses</b>                | <b>(67,716)</b> | <b>(39,066)</b> |

The Company sponsors a 401(k) retirement plan for its U.S. employees. The plan allows eligible employees to voluntarily defer a portion of their annual compensation on a pre-tax basis, subject to the maximum annual amounts as set periodically by the IRS. The Company makes matching contributions of 100% of the first 3% of employee contributions and 50% of the next 2% of employee contributions. The NL Plan provides for a monthly, pre-tax contribution by the Company of 15% of an employee's gross income, subject to statutory maximums. The Company made matching contributions of \$398 thousand and \$120 thousand for the years ended December 31, 2024 and 2023, respectively. Company contributions vest immediately for each participant.

For the years ended December 31, 2024 and 2023, other employee benefits also include employee health insurance and workers compensation insurance costs amounting to \$1.156 million and \$466

thousand, employment taxes amounting to \$966 thousand and \$319 thousand, respectively.

#### Note 8 — Current Prepayments and Other Receivables

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

| <i>(In thousands of USD)</i>                   | As at December 31, |              |
|------------------------------------------------|--------------------|--------------|
|                                                | 2024               | 2023         |
| Prepaid research and development costs         | 5,704              | 2,337        |
| Other prepaid expenses                         | 2,214              | 2,122        |
| License fee receivable                         | 14,285             | —            |
| Value added tax receivable                     | 321                | 1,006        |
| Share-based payment receivable                 | 4,951              | —            |
| Other receivables                              | 1,748              | 875          |
| <b>Total prepayments and other receivables</b> | <b>29,223</b>      | <b>6,340</b> |

The share-based payment receivable represents amounts due to the company on the exercise of vested options.

#### Note 9 — Accrued Expenses and other Current Liabilities

Accrued expenses and other current liabilities consisted of the following items as of December 31:

| <i>(in thousands of USD)</i>                                | As at December 31, |               |
|-------------------------------------------------------------|--------------------|---------------|
|                                                             | 2024               | 2023          |
| Accrued research and development materials and services     | 2,069              | 5,945         |
| Accrued compensation and benefits                           | 16,014             | 6,864         |
| Accrued professional fees and other                         | 2,818              | 2,069         |
| <b>Total accrued expenses and other current liabilities</b> | <b>20,901</b>      | <b>14,878</b> |

#### Note 10 — 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 2024 and 2023 in the Netherlands of 19% for the first €200,000 and 25.8% thereafter and the effective income tax rates for the Company, together with the corresponding amounts, for the years ended December 31:

|                                                                                    | 2024            | 2023          |
|------------------------------------------------------------------------------------|-----------------|---------------|
| Loss before tax                                                                    | (245,776)       | (178,587)     |
| <b>Income tax benefit at statutory tax rate</b>                                    | <b>(63,354)</b> | <b>46,020</b> |
| <b>Difference due to the effects of:</b>                                           |                 |               |
| Movement in unrecognized deferred tax assets resulting from carried forward losses | 63,354          | (46,020)      |
| <b>Income tax expense:</b>                                                         | <b>—</b>        | <b>—</b>      |
| <b>Effective tax rate:</b>                                                         | <b>0%</b>       | <b>0%</b>     |

### *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, 2024, 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, 2024 and 2023, the Group had assessed losses amounting to \$245.8 million and \$178.6 million, respectively. In addition, the Group assumed carry forward losses from the following tax periods, resulting from the fiscal unity of the Company, NewAmsterdam Pharma Holding B.V. and NewAmsterdam Pharma B.V. as associated with the acquisition of its assets and liabilities:

| Year      | Tax loss       |
|-----------|----------------|
| 2012-2013 | 7,842          |
| 2014      | 13,597         |
| 2015      | 30,117         |
| 2016      | 95,634         |
| 2017      | 1,462          |
| 2018      | 2,139          |
| 2019      | 1,577          |
| 2020      | 6,898          |
| 2021      | 18,848         |
| 2022      | 39,581         |
| 2023      | 70,029         |
| 2024      | 142,121        |
|           | <u>429,845</u> |

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 11 — Property, Plant and Equipment**

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

(in thousands of USD)

|                                      | Right of Use<br>Asset | Computer<br>Equipment | Furniture and<br>Fixtures | Total |
|--------------------------------------|-----------------------|-----------------------|---------------------------|-------|
| <b>(i) Cost</b>                      |                       |                       |                           |       |
| At 31 December 2022                  | 196                   | 49                    | —                         | 245   |
| Additions                            | —                     | 24                    | —                         | 24    |
| At 31 December 2023                  | 196                   | 73                    | —                         | 269   |
| <b>(ii) Accumulated depreciation</b> |                       |                       |                           |       |
| At 31 December 2022                  | 76                    | 15                    | —                         | 91    |
| Depreciation                         | 65                    | 12                    | —                         | 77    |
| At 31 December 2023                  | 141                   | 27                    | —                         | 168   |
| <b>(iii) Net book value</b>          |                       |                       |                           |       |
| At 31 December 2022                  | 120                   | 34                    | —                         | 154   |
| At 31 December 2023                  | 55                    | 46                    | —                         | 101   |

(in thousands of USD)

|                                      | Right of Use<br>Asset | Computer<br>Equipment | Furniture and<br>Fixtures | Total |
|--------------------------------------|-----------------------|-----------------------|---------------------------|-------|
| <b>(i) Cost</b>                      |                       |                       |                           |       |
| At 31 December 2023                  | 196                   | 73                    | —                         | 269   |
| Additions                            | 562                   | 165                   | 80                        | 807   |
| At 31 December 2024                  | 758                   | 238                   | 80                        | 1,076 |
| <b>(ii) Accumulated depreciation</b> |                       |                       |                           |       |
| At 31 December 2023                  | 141                   | 27                    | —                         | 168   |
| Depreciation                         | 186                   | 27                    | 22                        | 235   |
| At 31 December 2024                  | 327                   | 54                    | 22                        | 403   |
| <b>(iii) Net book value</b>          |                       |                       |                           |       |
| At 31 December 2023                  | 55                    | 46                    | —                         | 101   |
| At 31 December 2024                  | 431                   | 184                   | 58                        | 673   |

The Group leases office premises in Florida and Pennsylvania. Refer to Note 20 for lease liability details related to the right of use asset.

## Note 12 — 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 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 (translated at the per share price of \$9.87 at the Closing Date), the issuance of an aggregate of 8,656,330 Ordinary Shares increased equity by \$85.4 million (see Note 17). 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 \$85.4 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 13 — 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, marketable securities and other receivables and cash and cash equivalents, 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 analysis in the following sections relate to the position as of December 31, 2024 and 2023.

#### **Interest rate risk**

We are exposed to interest rate risk primarily through our cash, cash equivalents and marketable securities. Changes in interest rates may cause variations in interest income and expense resulting from short-term interest-bearing assets. We invest in high-quality financial instruments, primarily money

market funds and U.S. government and agency securities with maturities of less than one year, which we believe are subject to limited credit risk. We regularly review our investments and monitor the financial markets and we do not currently hedge interest rate exposure. Due to the nature of our investments, we do not believe an immediate 100 basis point change in interest rates would have a material effect on our financial condition. We do not believe that we have any material exposure to interest rate risk or changes in credit ratings arising from our investments.

### 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:

|               | <u>Increase / (decrease)</u><br><u>in basis points</u> | <u>Increase/ (decrease)</u><br><u>on</u><br><u>profit before tax/</u><br><u>Equity</u> |
|---------------|--------------------------------------------------------|----------------------------------------------------------------------------------------|
| <b>2023</b>   |                                                        |                                                                                        |
| British Pound | 100                                                    | —                                                                                      |
| British Pound | (100)                                                  | —                                                                                      |
| Euro          | 100                                                    | (1,248)                                                                                |
| Euro          | (100)                                                  | 1,248                                                                                  |
| U.S. Dollar   | 100                                                    | (2,156)                                                                                |
| U.S. Dollar   | (100)                                                  | 2,156                                                                                  |
| <b>2024</b>   |                                                        |                                                                                        |
| British Pound | 100                                                    | (30)                                                                                   |
| British Pound | (100)                                                  | 30                                                                                     |
| Euro          | 100                                                    | (957)                                                                                  |
| Euro          | (100)                                                  | 957                                                                                    |
| U.S. Dollar   | 100                                                    | (7,358)                                                                                |
| U.S. Dollar   | (100)                                                  | 7,358                                                                                  |

### 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 Group's functional currency of the Group, U.S. Dollar. As of December 31, 2024 the Group's net exposure to foreign currency risk amounts to \$108.6 million primarily arising from exposure to the Euro. As of December 31, 2024, the effect of a hypothetical 1% change in exchange rates on currencies denominated in other than our functional currency would result in a potential change in future earnings in our consolidated statement of operations of approximately \$1.1 million.

The Group partly manages its foreign currency risk by selectively holding foreign currency in its cash to offset foreign currency exposures from lease 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.

### Foreign currency sensitivity

The Group is mainly exposed to the currency of Euro, British Pound Sterling and Japanese Yen.

The following table demonstrates the sensitivity to a possible change in exchange rates against the US Dollar 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 USD | Effect on profit / (loss)<br>before tax |                     |
|---------------------------------------------|-----------------------------------------|---------------------|
|                                             | 10%<br>depreciation                     | 10%<br>appreciation |
| <b>2023</b>                                 |                                         |                     |
| British Pound Sterling                      | (74)                                    | 91                  |
| Chinese Yen                                 | —                                       | —                   |
| Euro                                        | (10,309)                                | 12,600              |
| Japanese Yen                                | (10)                                    | 13                  |
| Swedish Krona                               | —                                       | 1                   |
| <b>2024</b>                                 |                                         |                     |
| British Pound Sterling                      | (263)                                   | 321                 |
| Chinese Yen                                 | (25)                                    | 31                  |
| Euro                                        | (9,572)                                 | 11,699              |
| Japanese Yen                                | (9)                                     | 12                  |
| Swedish Krona                               | (1)                                     | 1                   |

### Other Market Price Risk

As a result of the Merger with FLAC in 2022, the Company has derivative warrant liabilities and a derivative earnout liability which are measured at FVTPL (see Note 14). At December 31, 2024, derivative warrant liabilities and derivative earnout liability amount to \$37.5 million and \$44.8 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:

|                                              | <b>% Increase /<br/>(decrease) in<br/>share price (NAMS /<br/>NAMSW)</b> | <b>Increase/ (decrease)<br/>in<br/>profit or loss before<br/>tax/equity</b> |
|----------------------------------------------|--------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| <b>2023</b>                                  |                                                                          |                                                                             |
| Derivative warrant liabilities (under NAMSW) | 14                                                                       | (1,760)                                                                     |
| Derivative warrant liabilities (under NAMSW) | (14)                                                                     | 1,760                                                                       |
| Derivative earnout liability (under NAMS)    | 14                                                                       | (1,090)                                                                     |
| Derivative earnout liability (under NAMS)    | (14)                                                                     | 1,090                                                                       |
| <b>2024</b>                                  |                                                                          |                                                                             |
| Derivative warrant liabilities (under NAMSW) | 14                                                                       | (5,252)                                                                     |
| Derivative warrant liabilities (under NAMSW) | (14)                                                                     | 5,252                                                                       |
| Derivative earnout liability (under NAMS)    | 14                                                                       | (6,272)                                                                     |
| Derivative earnout liability (under NAMS)    | (14)                                                                     | 6,272                                                                       |

### ***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 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, 2024 and 2023, is the carrying amount as illustrated in Note 8 (excluding prepayments) and Note 9.

### ***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 the market offering of the company’s ordinary shares, 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 and the amounts paid in respect of the clinical milestone achievement (see Note 4), and the equity funding from

the Merger with FLAC which occurred in 2022 resulting in the cash and cash equivalents balance of \$717.7 million at December 31, 2024 (see Note 15).

### 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, 2024 and 2023.

|                                        | <u>On demand</u> | <u>Less than<br/>3 months</u> | <u>3 - 12<br/>months</u> | <u>More than<br/>1 year</u> | <u>Total</u>   |
|----------------------------------------|------------------|-------------------------------|--------------------------|-----------------------------|----------------|
| <b>At December 31, 2023</b>            |                  |                               |                          |                             |                |
| Trade and other payables               | —                | 16,923                        | —                        | —                           | 16,923         |
| Accrued expenses and other liabilities | —                | 11,398                        | —                        | —                           | 11,398         |
| Share based payment liabilities        | 3,480            | —                             | —                        | —                           | 3,480          |
| Lease liability                        | —                | 17                            | 43                       | —                           | 60             |
| Derivative warrant liabilities         | 12,574           | —                             | —                        | —                           | 12,574         |
| Derivative earnout liability           | —                | —                             | —                        | 7,788                       | 7,788          |
| <b>Total financial liabilities</b>     | <u>16,054</u>    | <u>28,338</u>                 | <u>43</u>                | <u>7,788</u>                | <u>52,223</u>  |
|                                        | <u>On demand</u> | <u>Less than<br/>3 months</u> | <u>3 - 12<br/>months</u> | <u>More than<br/>1 year</u> | <u>Total</u>   |
| <b>At December 31, 2024</b>            |                  |                               |                          |                             |                |
| Trade and other payables               | —                | 4,744                         | —                        | —                           | 4,744          |
| Accrued expenses and other liabilities | —                | 20,901                        | —                        | —                           | 20,901         |
| Lease liability                        | —                | 59                            | 187                      | 202                         | 448            |
| Derivative warrant liabilities         | 37,514           | —                             | —                        | —                           | 37,514         |
| Derivative earnout liability           | —                | —                             | —                        | 44,799                      | 44,799         |
| <b>Total financial liabilities</b>     | <u>37,514</u>    | <u>25,704</u>                 | <u>187</u>               | <u>45,001</u>               | <u>108,406</u> |

### 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 14 — 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 FLAC Merger in 2022, 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 4,6 million 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 1,384,640 existing Warrants were exercised or redeemed from the Closing Date to December 31, 2024. At December 31, 2024, the Group had a total of 2,632,581 Warrants and Private Placement Warrants outstanding.

Both Private Placement Warrants and Public Warrants entitle the holder to convert each warrant into one Ordinary Share of the Company of \$0.13 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 \$1.23 per warrant as of the December 31, 2023 to \$7.25 per warrant at December 31, 2024. Consequently, for the year ended December 31, 2024, the Group has recognized a charge of \$38.6 million in profit or loss (December 31, 2023: \$10 million), 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***

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, 2024, 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 \$6.8 million. The financial liability was remeasured at December 31, 2024 which resulted in a charge of \$37 million in profit or loss (December 31, 2023: \$0.3 million), 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, 2024 | December 31, 2023 |
|-------------------------------------|-------------------|-------------------|
| Share value (USD)                   | 25.70             | 11.17             |
| Probability of milestone completion | 100%              | 40%               |
| Dividend yield                      | 0%                | 0%                |
| Strike price (USD)                  | 0.00              | 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, 2024. The resulting per share fair value of the Earnout Shares allocated to Participating Shareholders is \$6.70 at December 31, 2024, compared to a per share fair value of \$4.70 at December 31, 2023.

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:

|                                                         | December 31, 2024                                                   | December 31, 2023                                                   |
|---------------------------------------------------------|---------------------------------------------------------------------|---------------------------------------------------------------------|
|                                                         | Increase/ (decrease)<br>on profit before<br>tax/equity (in \$'000s) | Increase/ (decrease)<br>on profit before<br>tax/equity (in \$'000s) |
| <b>Changes to parameters</b>                            |                                                                     |                                                                     |
| Increase in probability of milestone achievement by 20% | —                                                                   | (3,894)                                                             |
| Decrease in probability of milestone achievement by 20% | 8,960                                                               | 3,894                                                               |

Refer to Note 13 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 \$37 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:

|                                                           | As of December 31, 2024 |         |         |        |
|-----------------------------------------------------------|-------------------------|---------|---------|--------|
| (In thousands of USD)                                     | Level 1                 | Level 2 | Level 3 | Total  |
| Derivative warrant liability (Public Warrants)            | 35,134                  | —       | —       | 35,134 |
| Derivative warrant liability (Private Placement Warrants) | —                       | 2,380   | —       | 2,380  |
| Derivative earnout liability                              | —                       | —       | 44,799  | 44,799 |
| Total financial liabilities                               | 35,134                  | 2,380   | 44,799  | 82,313 |

|                                                           | As of December 31, 2023 |         |         |        |
|-----------------------------------------------------------|-------------------------|---------|---------|--------|
| (In thousands of USD)                                     | Level 1                 | Level 2 | Level 3 | Total  |
| Derivative warrant liability (Public Warrants)            | 12,051                  | —       | —       | 12,051 |
| Derivative warrant liability (Private Placement Warrants) | —                       | 523     | —       | 523    |
| Derivative earnout liability                              | —                       | —       | 7,788   | 7,788  |
| Total financial liabilities                               | 12,051                  | 523     | 7,788   | 20,362 |

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

|                                                | Lease liability | Derivative<br>earnout<br>liability | Derivative<br>warrant<br>liabilities | Total liabilities<br>from<br>financing<br>activities |
|------------------------------------------------|-----------------|------------------------------------|--------------------------------------|------------------------------------------------------|
| <b>At January 1, 2024</b>                      | <b>60</b>       | <b>7,788</b>                       | <b>12,574</b>                        | <b>20,422</b>                                        |
| Principal paid on lease liabilities            | (174)           | —                                  | —                                    | (174)                                                |
| Interest paid on lease liabilities             | (26)            | —                                  | —                                    | (26)                                                 |
| Warrants exercised                             | —               | —                                  | (13,643)                             | (13,643)                                             |
| <b>Total changes from financing cash flows</b> | <b>(200)</b>    | <b>—</b>                           | <b>(13,643)</b>                      | <b>(13,843)</b>                                      |
| Interest charges                               | 26              | —                                  | —                                    | 26                                                   |
| Change in fair value                           | —               | 37,011                             | 38,583                               | 75,594                                               |
| Capital increases                              | 562             | —                                  | —                                    | 562                                                  |
| <b>Total liability-related charges</b>         | <b>588</b>      | <b>37,011</b>                      | <b>38,583</b>                        | <b>75,620</b>                                        |
| <b>At December 31, 2024</b>                    | <b>448</b>      | <b>44,799</b>                      | <b>37,514</b>                        | <b>82,199</b>                                        |

|                                                | Lease liability | Derivative<br>earnout<br>liability | Derivative<br>warrant<br>liabilities | Total liabilities<br>from<br>financing<br>activities |
|------------------------------------------------|-----------------|------------------------------------|--------------------------------------|------------------------------------------------------|
| <b>At January 1, 2023</b>                      | <b>126</b>      | <b>7,522</b>                       | <b>4,147</b>                         | <b>11,795</b>                                        |
| Principal paid on lease liabilities            | (66)            | —                                  | —                                    | (66)                                                 |
| Interest paid on lease liabilities             | (6)             | —                                  | —                                    | (6)                                                  |
| Warrants exercised                             | —               | —                                  | (1,591)                              | (1,591)                                              |
| <b>Total changes from financing cash flows</b> | <b>(72)</b>     | <b>—</b>                           | <b>(1,591)</b>                       | <b>(1,663)</b>                                       |
| Interest charges                               | 6               | —                                  | —                                    | 6                                                    |
| Change in fair value                           | —               | 266                                | 10,018                               | 10,284                                               |
| <b>Total liability-related charges</b>         | <b>6</b>        | <b>266</b>                         | <b>10,018</b>                        | <b>10,290</b>                                        |
| <b>At December 31, 2023</b>                    | <b>60</b>       | <b>7,788</b>                       | <b>12,574</b>                        | <b>20,422</b>                                        |

## Note 15 — Cash and cash equivalents

Cash and cash equivalents consisted of the following items as at December 31:

|                                           | 2024           | 2023           |
|-------------------------------------------|----------------|----------------|
| Cash at banks                             | 733.826        | 340.450        |
| Money market funds (Level 1)              | 25.444         | —              |
| US government agency securities (Level 2) | 12.473         | —              |
| <b>Cash and cash equivalents</b>          | <b>771.743</b> | <b>340.450</b> |

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

## Note 16 — Marketable Securities

Marketable securities held by the Company as of December 31 are as follows:

| (In thousands of USD)                                         | As at December 31, 2024 |                  |                   |            |
|---------------------------------------------------------------|-------------------------|------------------|-------------------|------------|
|                                                               | Amortized Cost          | Unrealized gains | Unrealized losses | Fair Value |
| Marketable securities                                         |                         |                  |                   |            |
| US government securities due within one year (Level 1)        | 37,711                  | 34               | —                 | 37,745     |
| US government agency securities due within one year (Level 2) | 24,691                  | 11               | —                 | 24,702     |
| Total marketable securities                                   | 62,402                  | 45               | —                 | 62,447     |

## Note 17 — Share Capital and Share Premium

The following table details the total share capital and share premium of the Group as at December 31, 2024 and 2023:

|                                                                                                         | Shares             | Price per share (in \$) | Share Capital (in \$'000) | Share Premium (in \$'000) | Total (in \$'000) |
|---------------------------------------------------------------------------------------------------------|--------------------|-------------------------|---------------------------|---------------------------|-------------------|
| <b>At December 31, 2022<sup>(1)</sup></b>                                                               | <b>81,559,780</b>  | <b>0.12</b>             | <b>10,055</b>             | <b>630,608</b>            | <b>640,663</b>    |
| Exercise of warrants                                                                                    | 749,741            | 0.13                    | 97                        | 10,116                    | 10,213            |
| Exercise of stock options                                                                               | 160,247            | 0.13                    | 21                        | 486                       | 507               |
| <b>At December 31, 2023<sup>(2)</sup></b>                                                               | <b>82,469,768</b>  | <b>0.13</b>             | <b>10,173</b>             | <b>641,210</b>            | <b>651,383</b>    |
| February 2024 Issuance of Ordinary Shares and Pre-Funded Warrants, net of issuance costs <sup>(3)</sup> | 5,871,909          | 0.13                    | 759                       | 189,206                   | 189,965           |
| December 2024 Issuance of Ordinary Shares and Pre-Funded Warrants, net of issuance costs <sup>(4)</sup> | 14,667,347         | 0.13                    | 1,851                     | 451,564                   | 453,415           |
| Exercise of Pre-Funded Warrants                                                                         | 2,105,248          | 0.13                    | 279                       | (279)                     | —                 |
| Exercise of warrants                                                                                    | 1,288,790          | 0.13                    | 168                       | 27,673                    | 27,841            |
| Exercise of stock options                                                                               | 1,661,278          | 0.13                    | 214                       | 8,791                     | 9,005             |
| <b>At December 31, 2024<sup>(5)</sup></b>                                                               | <b>108,064,340</b> | <b>0.13</b>             | <b>13,444</b>             | <b>1,318,165</b>          | <b>1,331,609</b>  |

- (1) 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 \$10.1 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.
- (2) At December 31, 2023 New Amsterdam Pharma had 82,469,768 ordinary shares with a par value of \$0.13 per share, resulting in a share capital of \$10.2 million. The share premium amounted to \$641.2 million after the exercise of 749,741 warrants and 160,247 stock options during the year.
- (3) On February 16, 2024, the Company completed an underwritten public offering (the “February 2024 Offering”) of 5,871,909 Ordinary Shares at a public offering price of \$19.00 per Ordinary Share and, in lieu of Ordinary Shares to certain investors, pre-funded warrants (“Pre-Funded Warrants”) to purchase 4,736,841 Ordinary Shares at a public offering price of \$18.9999 per Pre-Funded Warrant, which represents the per share public offering price for the Ordinary Shares, less the \$0.0001 per share exercise price for each such Pre-Funded Warrant. Of the 5,871,909 Ordinary Shares issued and sold in the February 2024 Offering, 1,383,750 Ordinary Shares were issued and sold pursuant to the exercise of the underwriters’ option to purchase additional Ordinary Shares at the public offering price per share. The net proceeds to the Company from the February 2024

Offering were \$190.0 million after deducting underwriting discounts and commissions and offering expenses payable by the Company. As of December 31, 2024 a total of 2,105,248 of the Pre-Funded Warrants issued in connection with the February 2024 Offering have been exercised, resulting in the issuance of 2,105,248 Ordinary Shares.

- (4) On December 13, 2024, the Company completed an underwritten public offering (the “December 2024 Offering”) of 14,667,347 Ordinary Shares at a public offering price of \$24.50 per Ordinary Share and, in lieu of Ordinary Shares to certain investors, Pre-Funded Warrants to purchase 4,882,653 Ordinary Shares at a public offering price of \$24.4999 per Pre-Funded Warrant, which represents the per share public offering price for the Ordinary Shares, less the \$0.0001 per share exercise price for each such Pre-Funded Warrant. Of the 14,667,347 Ordinary Shares issued and sold in the December 2024 Offering, 2,550,000 Ordinary Shares were issued and sold pursuant to the exercise of the underwriters’ option to purchase additional Ordinary Shares at the public offering price per share. The net proceeds to the Company from the December 2024 Offering were \$453.4 million after deducting underwriting discounts and commissions and offering expenses payable by the Company. As of December 31, 2024 none of the Pre-Funded Warrants issued in connection with the December 2024 Offering have been exercised.
- (5) At December 31, 2024 New Amsterdam Pharma had 108,064,340 ordinary shares with a par value of \$0.13 per share, resulting in a share capital of \$13.4 million. The share premium amounted to \$1,318 million after the exercise of 1,288,790 warrants and 1,661,278 stock options during the year.

## **Note 18 — Share-Based Payments**

The Company has four Share-based payment plans and one restricted share award in place as at December 31, 2024:

- The Company’s Long-Term Incentive Plan (the “Plan”);
- The Company’s Supplementary Long-Term Incentive Plan (the “Supplementary Plan”);
- The Company’s Rollover Option Plan (the “Rollover Plan,”);
- The Company’s Inducement Plan (the “Inducement Plan,” together with the Plan, the Supplementary Plan and the Rollover Plan, the “Plans”); and
- Chief Executive Officer Restricted Share Award.

### ***Long Term Incentive Plans***

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”) and restricted stock units (“RSUs”), pursuant to the Plans. In total, as of December 31, 2024 a maximum of 22,049,356 Ordinary Shares may be reserved for issuance pursuant to the Plans. The number of Ordinary Shares reserved for grant under the Plan will increase annually on January 1 of each calendar year by 5% of the then issued and outstanding Ordinary Shares or such lower number as may be determined by the Board of Directors.

### ***Term and Vesting Period***

The contractual term is 10 years from grant date for options granted under the Plans. In general, each Company Option granted in 2024 has a four-year vesting period with 25% vesting after one year and the remaining 75% vesting in equal monthly instalments over the next following three years.

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.

#### *Modifications of Options During the Year*

In 2024, a total of 399,153 Company Options granted to one employee were modified. For 210,655 of the modified Company Options the vesting period was shortened, of which 200,655 such modified Company Options also had the exercise period extended. For the other 188,498 modified Company Options only the exercise period was extended. The total fair value of the 210,655 modified Company Options for which the vesting period was shortened is equal to \$1.2 million. Any expense previously recognized for such Company Options was reversed on the modification date and the full fair value of the modified Company Options was recognized over the new applicable service period. For the 188,498 modified Company Options for which only the exercise period was extended the total fair value of the modification is equal to \$0.1 million, all of which is recognized on the modification date.

In 2023, the vesting period was shortened for 490,067 Company Options granted to an employee in relation with the signing of an employment separation agreement. At the modification date, 255,243 Company Options were expected to vest both under the original and the modified vesting conditions. For these Company Options, the modification did not result in any incremental compensation cost. For the 234,824 Company Options that were not probable to vest as of the modification date based on the original terms, the incremental fair value granted is equal to the fair value of the modified award of \$12.19 (i.e., the value of the modified award, as determined on the modification date, compared to its prior zero value). In 2023, the total incremental fair value of \$2.9 million has been fully recognized over the remaining modified requisite service period.

The changes for the year ended December 31, 2024 in the number of options outstanding related to Ordinary Shares and their related weighted average exercise prices are as follows:

|                                             | Number of<br>options | Weighted<br>average<br>exercise<br>price USD | Weighted<br>average<br>remaining<br>contractual<br>term<br>(in years) | Aggregate<br>intrinsic<br>value<br>(in thousands<br>of USD) |
|---------------------------------------------|----------------------|----------------------------------------------|-----------------------------------------------------------------------|-------------------------------------------------------------|
| Outstanding as at December 31, 2023         | 15,783,509           | 7.98                                         |                                                                       |                                                             |
| Granted                                     | 5,275,448            | 14.28                                        |                                                                       |                                                             |
| Exercised                                   | (1,755,220)          | 3.93                                         |                                                                       |                                                             |
| Forfeited                                   | (274,681)            | 10.68                                        |                                                                       |                                                             |
| Outstanding as at December 31, 2024         | 19,029,056           | 10.04                                        | 8.2                                                                   | 297,977                                                     |
| Options exercisable as of December 31, 2024 | 7,884,500            | 7.14                                         | 7.5                                                                   | 146,330                                                     |

As at December 31, 2024, 7,884,500 of the outstanding Company Options are exercisable. The options outstanding as of December 31, 2024 and 2023 have a weighted average remaining contractual life of 8.2 years and 8.7 years, respectively.

#### *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:

|                       | Year ended December 31, |       |
|-----------------------|-------------------------|-------|
|                       | 2024                    | 2023  |
| Expected life (years) | 6.1                     | 6.1   |
| Risk-free rate        | 3.9%                    | 4.1%  |
| Volatility            | 41.8%                   | 38.1% |
| Dividend yield        | 0.0%                    | 0.0%  |

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 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 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.

#### *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, 2024 and 2023, the total share-based payment expense recognized for the equity-settled options amounted to \$33.6 million and \$24.6 million, respectively.

In addition, during the years ended December 31, 2024 and 2023, the Company recognized \$3,813 million and \$1,715 million as expenses for the employer social security contributions expected to be payable related to these options. The corresponding liability as of December 31, 2024 and 2023 amounts to \$7,293 million and \$3,480 million, respectively.

*Restricted Stock Units (“RSUs”)*

As at December 31, 2024 and 2023 the Company had allocated 143,002 and 143,002 Earnout Shares, respectively, to be granted to Participating Option holders 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 Option holders 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 the Company’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.

Prior to 2024 no expense was recognized in relation to the Earnout RSUs as the milestone was not deemed probable to occur. During 2024 the probability of the milestone completion was reassessed and the milestone was deemed probable to occur. Therefore, the Company began to recognize expense in relation to the Earnout RSUs. Refer to Note 14 regarding the financial statement impact of the Earnout Shares allocated to Participating Shareholders.

***Chief Executive Officer Restricted Share Award***

In July 2021, our chief executive officer, Michael Davidson, M.D., paid the fair market value of the underlying ordinary shares (in aggregate \$838,806) when he made an investment in restricted shares issued through Depositary Receipts. 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. This award had a four year vesting period with 25% vesting on August 1, 2021 and the remaining 75% vesting in equal monthly instalments over the following three years.

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, 2024 and 2023 amounts to nil and \$0.1 million, respectively. There is no outstanding liability as at December 31, 2024.

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

|                                   | 2024                         | 2023                                           |
|-----------------------------------|------------------------------|------------------------------------------------|
|                                   | Number of<br>Ordinary Shares | Number of<br>Ordinary<br>Shares <sup>(1)</sup> |
| Outstanding as at December 31,    | 608,779                      | 608,779                                        |
| Granted/purchased during the year | —                            | —                                              |
| Outstanding as at December 31,    | 608,779                      | 608,779                                        |

As of December 31, 2024 and 2023, in total 608,779 and 519,999 Ordinary Shares underlying the Founder DRs had vested, respectively.

#### Note 19 — 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.

The following table sets forth the basic and diluted loss per share for the year ended December 31:

|                                                                  | Year ended December 31, |            |
|------------------------------------------------------------------|-------------------------|------------|
|                                                                  | 2024                    | 2023       |
| <i>(In thousands of USD, except share and per share amounts)</i> |                         |            |
| Net loss                                                         | (245,775)               | (178,614)  |
| Weighted average ordinary shares outstanding, basic and diluted  | 94,358,067              | 82,161,956 |
| Net loss per ordinary share, basic and diluted                   | (2.60)                  | (2.17)     |

At December 31, 2024, and 2023, outstanding share-based awards (see Note 18) was excluded from the calculation because their impact would be anti-dilutive. At December 31, 2024 and 2023, the total number of potential ordinary shares excluded amounted to 19,029,056 and 15,783,509 respectively.

#### Note 20 — Lease

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

|                                       | 2024       | 2023       |
|---------------------------------------|------------|------------|
| <b>Opening balance at January 1</b>   | <b>55</b>  | <b>120</b> |
| Additions                             | 562        | —          |
| Depreciation                          | (186)      | (65)       |
| <b>Total ROU asset at December 31</b> | <b>431</b> | <b>55</b>  |

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

|                                             | 2024       | 2023       |
|---------------------------------------------|------------|------------|
| <b>Opening balance at January 1</b>         | <b>60</b>  | <b>126</b> |
| Additions                                   | 562        | —          |
| Repayment                                   | (200)      | (72)       |
| Interest                                    | 26         | 6          |
| <b>Total lease liability at December 31</b> | <b>448</b> | <b>60</b>  |
| <b>Current</b>                              |            |            |
| Lease liabilities                           | 246        | 60         |
| <b>Non-current</b>                          |            |            |
| Lease liabilities                           | 202        | —          |

With effective date May 29, 2021, the Company leases office premises in Florida set to expire October 31, 2024. This was extended to now expire on October 31, 2027. The company also leases office premises in PA set to expire April 3, 2026 effective April 2024. Refer to Note 11 for right of use lease asset details related to this finance lease liability.

#### **Note 21 — Related Parties**

In the ordinary course of business, the Company may enter into transactions with entities that are associated with a party that meets the criteria of a related party of the Company. These transactions are reviewed quarterly and to date have not been material to the Company's consolidated financial statements.

#### **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. During the year, KMPs have been identified as the Chief Executive Officer, Chief Financial Officer, and Chief Scientific Officer compared to prior year where KMPs included Chief Executive Officer, Chief Financial Officer, Chief Accounting 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:

|                                                            | 2024          | 2023          |
|------------------------------------------------------------|---------------|---------------|
| Short-term employee benefits                               | 2,854         | 3,958         |
| Share-based payments                                       | 11,943        | 18,229        |
| <b>Total compensation paid to key management personnel</b> | <b>14,797</b> | <b>22,187</b> |

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, 2024 and 2023 totaling \$428 thousand and \$331 thousand respectively, and share-based payment expenses during the period totaling \$810 thousand and \$469 thousand, respectively. John Kastelein M.D., non-executive director, received cash remuneration from the Company during the years ended December 31, 2024 and 2023 totaling \$812 thousand and \$682 thousand, respectively, and share-based payment expenses totaling \$3.054 thousand and \$3.521 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.

#### *2024 Board of Directors' remuneration*

| <i>(In thousands of USD)</i>   | Salary       | Bonus      | Management fee | Share-based compensation | Total remuneration 2024 |
|--------------------------------|--------------|------------|----------------|--------------------------|-------------------------|
| <b>Executive director</b>      |              |            |                |                          |                         |
| Michael Davidson, M.D.*        | 625          | 497        | —              | 6,818                    | 7,940                   |
| <b>Non-executive directors</b> |              |            |                |                          |                         |
| John Kastelein, M.D.*          | 486          | 327        | —              | 3,054                    | 3,867                   |
| Louis Lange, M.D., Ph.D.       | 58           | —          | —              | 199                      | 257                     |
| James N. Topper, M.D., Ph.D.   | 40           | —          | —              | —                        | 40                      |
| Juliette Audet**               | 10           | —          | —              | —                        | 10                      |
| Sander Slootweg**              | 20           | —          | —              | —                        | 20                      |
| Nicholas Downing, M.D.         | 44           | —          | —              | —                        | 44                      |
| John W. Smither                | 58           | —          | —              | 52                       | 110                     |
| Janneke van der Kamp           | 46           | —          | —              | 66                       | 112                     |
| William Lewis                  | 106          | —          | —              | 318                      | 424                     |
| Mark McKenna**                 | 26           | —          | —              | 174                      | 200                     |
| Wouter Joustra**               | 20           | —          | —              | —                        | 20                      |
| <b>Total</b>                   | <b>1,539</b> | <b>824</b> | <b>—</b>       | <b>10,681</b>            | <b>13,044</b>           |

\*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 2024.

\*\*Juliette Audet and Sander Slootweg resigned as members of the Board of Directors effective April 1, 2024 and July 1, 2024, respectively. Mark McKenna and Wouter Joustra joined the Board of Directors

effective July 16, 2024.

*2023 Board of Directors' remuneration*

| <i>(In thousands of USD)</i>   | <b>Salary</b> | <b>Bonus</b> | <b>Management<br/>fee</b> | <b>Share-based<br/>compensation</b> | <b>Total<br/>remuneration<br/>2023</b> |
|--------------------------------|---------------|--------------|---------------------------|-------------------------------------|----------------------------------------|
| <b>Executive director</b>      |               |              |                           |                                     |                                        |
| Michael Davidson, M.D.         | 573           | 313          | -                         | 8,329                               | 9,215                                  |
| <b>Non-executive directors</b> |               |              |                           |                                     |                                        |
| John Kastelein, M.D.           | 459           | 223          | -                         | 3,521                               | 4,203                                  |
| Louis Lange, M.D., Ph.D.       | 62            | -            | -                         | 377                                 | 439                                    |
| James N. Topper, M.D., Ph.D.   | 40            | -            | -                         | -                                   | 40                                     |
| Juliette Audet                 | 46            | -            | -                         | -                                   | 46                                     |
| Sander Slootweg                | 48            | -            | -                         | -                                   | 48                                     |
| Nicholas Downing, M.D.         | 47            | -            | -                         | -                                   | 47                                     |
| John W. Smither                | 56            | -            | -                         | 47                                  | 103                                    |
| Janneke van der Kamp           | 32            | -            | -                         | 45                                  | 77                                     |
| <b>Total</b>                   | <b>1,363</b>  | <b>536</b>   | <b>-</b>                  | <b>12,319</b>                       | <b>14,218</b>                          |

## Options held by the Board of Directors

|                                         | <u>Number of share<br/>options held as at<br/>December 31, 2024</u> | <u>Number of<br/>share options<br/>held as at<br/>December 31,<br/>2023</u> | <u>Exercise<br/>price per<br/>share</u> |
|-----------------------------------------|---------------------------------------------------------------------|-----------------------------------------------------------------------------|-----------------------------------------|
| <b>Executive director</b>               |                                                                     |                                                                             |                                         |
| Michael Davidson, M.D. <sup>(1)</sup>   | 989,267                                                             | 989,267                                                                     | € 1.16                                  |
| Michael Davidson, M.D. <sup>(2)</sup>   | 2,440,538                                                           | 2,440,538                                                                   | \$10.00                                 |
| Michael Davidson, M.D. <sup>(3)</sup>   | 1,021,485                                                           | 1,021,485                                                                   | \$10.90                                 |
| Michael Davidson, M.D. <sup>(6)</sup>   | 1,039,939                                                           | -                                                                           | \$11.17                                 |
| <b>Non-executive directors</b>          |                                                                     |                                                                             |                                         |
| John Kastelein, M.D. <sup>(1)</sup>     | 970,229                                                             | 1,171,902                                                                   | € 1.16                                  |
| John Kastelein, M.D. <sup>(2)</sup>     | 971,726                                                             | 971,726                                                                     | \$10.00                                 |
| John Kastelein, M.D. <sup>(3)</sup>     | 477,347                                                             | 477,347                                                                     | \$10.90                                 |
| John Kastelein, M.D. <sup>(6)</sup>     | 500,000                                                             | -                                                                           | \$11.17                                 |
| Louis Lange, M.D., Ph.D. <sup>(1)</sup> | 85,229                                                              | 85,229                                                                      | € 1.16                                  |
| Louis Lange, M.D., Ph.D. <sup>(2)</sup> | 84,957                                                              | 84,957                                                                      | \$10.00                                 |
| Louis Lange, M.D., Ph.D. <sup>(3)</sup> | 57,583                                                              | 57,583                                                                      | \$10.90                                 |
| Louis Lange, M.D., Ph.D. <sup>(6)</sup> | 10,000                                                              | -                                                                           | \$11.17                                 |
| John Smither <sup>(4)</sup>             | 18,600                                                              | 18,600                                                                      | \$10.22                                 |
| John Smither <sup>(6)</sup>             | 10,000                                                              | -                                                                           | \$11.17                                 |
| Janneke van der Kamp <sup>(5)</sup>     | 18,000                                                              | 18,000                                                                      | \$13.26                                 |
| Janneke van der Kamp <sup>(6)</sup>     | 10,000                                                              | -                                                                           | \$11.17                                 |
| William Lewis <sup>(7)</sup>            | 100,000                                                             | -                                                                           | \$12.01                                 |
| Mark McKenna <sup>(8)</sup>             | 72,500                                                              | -                                                                           | \$18.81                                 |

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. During the year, John Kastelein exercised 201,673 vested options.
- (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. Louis Lange exercised 9,878 vested options for the year ended December 31, 2023. No vested options held by the Board of Directors were exercised during the year ended December 31, 2022.

- (3) The grant date is January 1, 2023 and the final exercise date is December 31, 2032. 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.
- (4) The grant date is January 14, 2023 and the final exercise date is January 13, 2033. 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.
- (5) The grant date is April 1, 2023 and the final exercise date is March 31, 2033. 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.
- (6) The grant date is January 1, 2024 and the final exercise date is December 31, 2033. 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.
- (7) The grant date is January 4, 2024 and the final exercise date is January 3, 2034. 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.
- (8) The grant date is July 17, 2024 and the final exercise date is July 16, 2034. 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.

## **Note 22 — 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 \$45.6 million and \$14.1 million from the Menarini License during the

year ended December 31, 2024 and December 31, 2023 respectively 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:

|                           | 2024          | 2023          |
|---------------------------|---------------|---------------|
| <b>Non-current assets</b> |               |               |
| Netherlands               | 88,850        | 88,714        |
| USA                       | 521           | 120           |
| <b>Total</b>              | <b>89,371</b> | <b>88,834</b> |

### Note 23 — 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.

| <i>(In thousands of USD)</i> | For the Years Ended December 31, |              |
|------------------------------|----------------------------------|--------------|
|                              | 2024                             | 2023         |
| Audit Fees                   | 1,433                            | 1,525        |
| Audit-Related Fees           | —                                | —            |
| Tax Fees                     | —                                | —            |
| All Other Fees               | —                                | —            |
| <b>Total Fees</b>            | <b>1,433</b>                     | <b>1,525</b> |

### Note 24 — Events After the Reporting Period

There are no events after the reporting period.

## 8.2 Company Financial Statements

## STATEMENT OF FINANCIAL POSITION

December 31, 2024 and 2023

(before appropriation of the result)

|                                                              | Note | As at December<br>31, 2024 | As at December<br>31, 2023 |
|--------------------------------------------------------------|------|----------------------------|----------------------------|
| <i>(In thousands of USD)</i>                                 |      |                            |                            |
| <b>Assets</b>                                                |      |                            |                            |
| <b>Fixed assets</b>                                          |      |                            |                            |
| Financial fixed assets                                       | 1    | 725,965                    | 393,848                    |
| <b>Total fixed assets</b>                                    |      | <b>725,965</b>             | <b>393,848</b>             |
| <b>Current assets</b>                                        |      |                            |                            |
| Marketable Securities                                        |      | 62,447                     | —                          |
| Prepayments and other receivables                            | 2    | 8,496                      | 1,656                      |
| Cash                                                         |      | 135,281                    | 3,903                      |
| <b>Total current assets</b>                                  |      | <b>206,224</b>             | <b>5,559</b>               |
| <b>Short-term liabilities</b>                                |      |                            |                            |
| Trade and other payables                                     | 3    | 11,506                     | 5,605                      |
| Financial liabilities                                        | 4    | 37,514                     | 12,574                     |
| <b>Total short-term liabilities</b>                          |      | <b>49,020</b>              | <b>18,179</b>              |
| <b>Balance of current assets less short-term liabilities</b> |      | <b>157,204</b>             | <b>(12,620)</b>            |
| <b>Total assets less short-term liabilities</b>              |      | <b>883,169</b>             | <b>381,228</b>             |
| <b>Long-term liabilities</b>                                 |      |                            |                            |
| Financial liabilities                                        | 4    | 44,799                     | 7,788                      |
| <b>Total long-term liabilities</b>                           |      | <b>44,799</b>              | <b>7,788</b>               |
| <b>Equity</b>                                                | 5    |                            |                            |
| Paid-in and called-up capital                                |      | 13,444                     | 10,173                     |
| Share premium                                                |      | 1,318,165                  | 641,210                    |
| Other reserves                                               |      | 60,006                     | 29,572                     |
| Accumulated loss                                             |      | (307,984)                  | (129,370)                  |
| Loss for the period                                          |      | (245,775)                  | (178,614)                  |
| Cumulative currency translation                              |      | 469                        | 469                        |
| Unrealized gain on available-for-sale securities             |      | 45                         | —                          |
| <b>Total equity</b>                                          |      | <b>838,370</b>             | <b>373,440</b>             |
| <b>Total long-term liabilities plus equity</b>               |      | <b>883,169</b>             | <b>381,228</b>             |

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

## COMPANY STATEMENTS OF PROFIT OR LOSS

|                                       |      | Period ended<br>December<br>31, 2024 | Period ended<br>December<br>31, 2023 |
|---------------------------------------|------|--------------------------------------|--------------------------------------|
|                                       | Note |                                      |                                      |
| <i>(In thousands of USD)</i>          |      |                                      |                                      |
| Share in result of subsidiaries       | 1    | (152,502)                            | (153,947)                            |
| Other income and expenses after taxes | 6    | (93,273)                             | (24,667)                             |
| <b>Loss for the period after tax</b>  |      | <b>(245,775)</b>                     | <b>(178,614)</b>                     |

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

#### 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. The Company received proceeds of \$71.7 million as a result of the Business Combination and \$234.6 million as a result of the concurrent PIPE Financing in 2022. As at December 31, 2024 the Company had cash and cash equivalents of \$771,7 million. 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 2024 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.

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 have been prepared for a period of 12 months ending December 31, 2024, the end of the calendar year with comparatives ending December 31, 2023 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 1 (in the Notes to the consolidated financial statements).

Movements in the financial fixed assets is as follows:

| <i>(In thousands of USD)</i>         | <b>Investment in<br/>consolidated<br/>subsidiaries</b> | <b>Intercompany<br/>receivables</b> | <b>Total</b>   |
|--------------------------------------|--------------------------------------------------------|-------------------------------------|----------------|
| <b>Balance at January 1, 2023</b>    | <b>143,666</b>                                         | <b>385,861</b>                      | <b>529,527</b> |
| Investments                          | 18,623                                                 | —                                   | 18,623         |
| Decrease in intercompany receivables | —                                                      | (355)                               | (355)          |
| Share in results of subsidiaries     | (153,947)                                              | —                                   | (153,947)      |
| <b>Balance at December 31, 2023</b>  | <b>8,342</b>                                           | <b>385,506</b>                      | <b>393,848</b> |
| <b>Balance at January 1, 2024</b>    | <b>8,342</b>                                           | <b>385,506</b>                      | <b>393,848</b> |
| Investments                          | —                                                      | —                                   | —              |
| Increase in intercompany receivables | —                                                      | 484,619                             | 484,619        |
| Share in results of subsidiaries     | (152,502)                                              | —                                   | (152,502)      |
| <b>Balance at December 31, 2024</b>  | <b>(144,160)</b>                                       | <b>870,125</b>                      | <b>725,965</b> |

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, 2024 and 2023 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.

As at December 31, 2024 and 2023, the investment in subsidiaries, considering the intercompany receivables as an extension of the investment in the subsidiary, is carried at \$726 million and \$393.8 million, respectively, and does not include any provision for impairment.

| <u>Name</u>                                           | <u>Principal place of business</u> | <u>Country of incorporation</u> | <u>Percent equity interest 2024</u> | <u>Percent equity interest 2023</u> |
|-------------------------------------------------------|------------------------------------|---------------------------------|-------------------------------------|-------------------------------------|
| NewAmsterdam Pharma Holding B.V.                      | Naarden                            | The Netherlands                 | Directly 100%                       | Directly 100%                       |
| Frazier Lifesciences Acquisition Corporation ("FLAC") | Delaware, USA                      | United States of America        | Directly 100%                       | Directly 100%                       |
| NewAmsterdam Pharma B.V.                              | Naarden                            | The Netherlands                 | Indirectly 100%                     | Indirectly 100%                     |
| NewAmsterdam Pharma Corporation                       | Florida, USA                       | United States of America        | Indirectly 100%                     | Indirectly 100%                     |

## 2. Prepayments and other receivables

| <i>(In thousands of USD)</i>                   | <u>As at December 31, 2024</u> | <u>As at December 31, 2023</u> |
|------------------------------------------------|--------------------------------|--------------------------------|
| Prepaid insurance                              | 1,381                          | 1,556                          |
| Prepaid general and administrative             | 872                            | 20                             |
| Value added tax receivable                     | 1,292                          | 80                             |
| Share-based payment receivable                 | 4,951                          | —                              |
| <b>Total prepayments and other receivables</b> | <b>8,496</b>                   | <b>1,656</b>                   |

Reference is made to Note 8 in the consolidated financial statements for further information on Prepayments and other receivables.

### 3. Trade and other payables

| <i>(In thousands of USD)</i>          | <b>As at December<br/>31, 2024</b> | <b>As at December<br/>31, 2023</b> |
|---------------------------------------|------------------------------------|------------------------------------|
| Accounts payable                      | 1,913                              | 375                                |
| Accrued expenses                      | 1,428                              | 1,156                              |
| Accrued wages and bonuses             | 872                                | 484                                |
| Share based payment liabilities       | 7,293                              | 3,590                              |
| <b>Total trade and other payables</b> | <b>11,506</b>                      | <b>5,605</b>                       |

Reference is made to Note 9 in the consolidated financial statements for further information on Trade and other payables.

### 4. Financial liabilities

| <i>(In thousands of USD)</i>                     | <b>As at December<br/>31, 2024</b> | <b>As at December<br/>31, 2023</b> |
|--------------------------------------------------|------------------------------------|------------------------------------|
| Derivative earnout liability                     | 44,799                             | 7,788                              |
| <b>Total financial liabilities - non-current</b> | <b>44,799</b>                      | <b>7,788</b>                       |
| Derivative warrant liabilities                   | 37,514                             | 12,574                             |
| <b>Total financial liabilities - current</b>     | <b>37,514</b>                      | <b>12,574</b>                      |

Reference is made to Note 14 in the consolidated financial statements for further information on financial liabilities and Note 13 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 (Naamloze 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 \$27.3 million, as assumed by the Company, span from NewAmsterdam Pharma's inception until the date of the internal reorganization.

On December 31, 2024, the Company's authorized share capital amounted to \$480 million divided into 400 million ordinary shares, each with a nominal value of \$0.12. As at December 31, 2024, the total number of issued ordinary shares was 108,064,340. On December 31, 2024, the issued share capital totalled to \$13.4 million. No dividend was distributed in 2024.

| <i>(In thousands of USD)</i>                                    | <b>Paid-in<br/>and<br/>called-up<br/>capital</b> | <b>Share<br/>premium</b> | <b>Other<br/>reserves</b> | <b>Accumulated<br/>loss</b> | <b>Loss for<br/>the period,<br/>after tax</b> | <b>Other<br/>Comprehensive<br/>income</b> | <b>Cumulative<br/>translation<br/>adjustment</b> | <b>Total<br/>equity</b> |
|-----------------------------------------------------------------|--------------------------------------------------|--------------------------|---------------------------|-----------------------------|-----------------------------------------------|-------------------------------------------|--------------------------------------------------|-------------------------|
| <b>Opening balance at January 1, 2023</b>                       | <b>10,055</b>                                    | <b>630,608</b>           | <b>5,028</b>              | <b>(129,370)</b>            | <b>—</b>                                      | <b>—</b>                                  | <b>469</b>                                       | <b>516,790</b>          |
| Exercise of warrants                                            | 97                                               | 10,116                   | —                         | —                           | —                                             | —                                         | —                                                | 10,213                  |
| Exercise of stock options                                       | 21                                               | 486                      | (217)                     | —                           | —                                             | —                                         | —                                                | 290                     |
| Share-based compensation                                        | —                                                | —                        | 24,761                    | —                           | —                                             | —                                         | —                                                | 24,761                  |
| Loss for the period, after tax                                  | —                                                | —                        | —                         | —                           | (178,614)                                     | —                                         | —                                                | (178,614)               |
| <b>Balance at December 31, 2023</b>                             | <b>10,173</b>                                    | <b>641,210</b>           | <b>29,572</b>             | <b>(129,370)</b>            | <b>(178,614)</b>                              | <b>—</b>                                  | <b>469</b>                                       | <b>373,440</b>          |
| <b>Opening balance at January 1, 2024</b>                       | <b>10,173</b>                                    | <b>641,210</b>           | <b>29,572</b>             | <b>(307,984)</b>            | <b>—</b>                                      | <b>—</b>                                  | <b>469</b>                                       | <b>373,440</b>          |
| February Offering of Ordinary Shares and<br>Pre-Funded Warrants | 759                                              | 189,206                  | —                         | —                           | —                                             | —                                         | —                                                | 189,965                 |
| December Offering of Ordinary Shares and<br>Pre-Funded Warrants | 1,851                                            | 451,564                  | —                         | —                           | —                                             | —                                         | —                                                | 453,415                 |
| Exercise of Pre-Funded Warrants                                 | 279                                              | -279                     | —                         | —                           | —                                             | —                                         | —                                                | -                       |
| Exercise of warrants                                            | 168                                              | 27,673                   | —                         | —                           | —                                             | —                                         | —                                                | 27,841                  |
| Exercise of stock options                                       | 214                                              | 8,791                    | (3,295)                   | —                           | —                                             | —                                         | —                                                | 5,710                   |
| Share-based compensation                                        | —                                                | —                        | 33,729                    | —                           | —                                             | —                                         | —                                                | 33,729                  |
| Loss for the period, after tax                                  | —                                                | —                        | —                         | —                           | (245,775)                                     | 45                                        | —                                                | (245,730)               |
| <b>Balance at December 31, 2024</b>                             | <b>13,444</b>                                    | <b>1,318,165</b>         | <b>60,006</b>             | <b>(307,984)</b>            | <b>(245,775)</b>                              | <b>45</b>                                 | <b>469</b>                                       | <b>838,370</b>          |

During the period under review, no dividend was distributed out of the Company's accumulated loss. The managing directors propose to allocate the net loss for the period to the accumulated loss. The proposed appropriation of loss has not been reflected in the Company's balance sheet per December 31, 2024.

## 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 \$553.8 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, 2024.

## 6. Other income and expenses after taxes

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

| <i>(In thousands of USD)</i>                       | <b>Period ended<br/>December<br/>31, 2024</b> | <b>Period ended<br/>December<br/>31, 2023</b> |
|----------------------------------------------------|-----------------------------------------------|-----------------------------------------------|
| Management fee                                     | 1.992                                         | 4.784                                         |
| Research and development expenses                  | (6.494)                                       | (6.589)                                       |
| General and administrative expenses                | (17.940)                                      | (12.819)                                      |
| Finance income                                     | 7.308                                         | 213                                           |
| Finance expense                                    | (6)                                           | —                                             |
| Change in fair value - earnout and warrants        | (75.593)                                      | (10.284)                                      |
| Net foreign exchange gains/(losses)                | (2.540)                                       | 28                                            |
| <b>Total other income and expenses after taxes</b> | <b>(93.273)</b>                               | <b>(24.667)</b>                               |

## 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 10 in the consolidated financial statements for further information on Income Taxes.

## 8. Employees and employee information

The Company employed 8 full-time employees in 2024 (2023: 5), all of which were employed within the Netherlands.

Reference is made to Note 21 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 18 in the consolidated financial statements for disclosure on the share-based payments.

## **9. Remuneration of the Board of Directors**

Reference is made to Note 21 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 21 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 23 in the consolidated financial statements.

## **12. Events after the reporting period**

Reference is made to Note 24 in the consolidated financial statements.

# **9 OTHER INFORMATION**

## **9.1 Independent auditor's report**

## INDEPENDENT AUDITOR'S REPORT

To: The shareholders and the supervisory board of NewAmsterdam Pharma Company N.V.

### Report on the audit of the financial statements for the year ended 31 December 2024 included in the annual report

#### Our opinion

We have audited the financial statements for the year ended 31 December 2024 of NewAmsterdam Pharma Company N.V. (the "Company"), based in Naarden, the Netherlands. The financial statements comprise of 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 31 December 2024, and of its result and its cash flows for the year ended 31 December 2024 in accordance with International Financial Reporting Standards as adopted by the European Union (EU-IFRS) and with Part 9 of Book 2 of the Dutch Civil Code.
- The accompanying company financial statements give a true and fair view of the financial position of NewAmsterdam Pharma Company N.V. as at 31 December 2024, and of its result for the year ended 31 December 2024 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 31 December 2024.
2. The following statements for the year ended 31 December 2024: the consolidated statement of profit or loss and comprehensive income, consolidated statements of changes in equity and consolidated statements of cash flows.
3. The notes comprising a summary of significant accounting policies and other explanatory information.

The company financial statements comprise:

1. The company statement of financial position as at 31 December 2024.
2. The company statements of profit or loss for the period ended 31 December 2024.
3. The notes comprising a summary of significant accounting policies and other explanatory information.

Deloitte Accountants B.V. is registered with the Trade Register of the Chamber of Commerce under number 24362853. Deloitte Accountants B.V. is a Netherlands affiliate of Deloitte NSE LLP, a member firm of Deloitte Touche Tohmatsu Limited.

## **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 firms supervision act, 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 for Professional Accountants).

We believe the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

## **Information in support of our opinion**

We designed our audit procedures in the context of our audit of the financial statements as a whole and in forming our opinion thereon. The following information in support of our opinion was addressed in this context, and we do not provide a separate opinion or conclusion on these matters.

### **Scope of the group audit**

NewAmsterdam Pharma Company N.V. is at the head of a group of components. The financial information of this group is included in the financial statements of NewAmsterdam Pharma Company N.V.

Based on our risk assessment, we determined the nature, timing and extent of audit procedures to be performed, including determining the components at which to perform audit procedures.

By performing the procedures mentioned above at components, together with additional procedures at group level, we have been able to obtain sufficient and appropriate audit evidence about the group's financial information to provide an opinion on the financial statements.

### **Audit approach fraud risks**

We identified and assessed the risks of material misstatements of the financial statements due to fraud. During our audit we obtained an understanding of the company and its environment and the components of the system of internal control, including the risk assessment process and management's process for responding to the risks of fraud and monitoring the system of internal control and how the supervisory board exercises oversight, as well as the outcomes.

We evaluated the design and relevant aspects of the system of internal control and in particular the fraud risk assessment, as well as among others the code of conduct, whistle blower procedures and incident registration. We evaluated the design and the implementation and, where considered appropriate, tested the operating effectiveness, of internal controls designed to mitigate fraud risks.

As part of our process of identifying fraud risks, we evaluated fraud risk factors with respect to financial reporting fraud, misappropriation of assets and bribery and corruption. We evaluated whether these factors indicate that a risk of material misstatement due to fraud is present.

We identified the following fraud risks and performed the following specific procedures:

- We incorporated elements of unpredictability in our audit. We also considered the outcome of our other audit procedures and evaluated whether any findings were indicative of fraud or non-compliance.

- We considered available information and made enquiries of relevant executives and the Board of Directors.
- We tested the appropriateness of journal entries recorded in the general ledger and other adjustments made in the preparation of the financial statements.
- We evaluated whether the selection and application of accounting policies by the group, particularly those related to subjective measurements and complex transactions, may be indicative of fraudulent financial reporting.
- We evaluated whether the judgments and decisions made by management in making the accounting estimates included in the financial statements indicate a possible bias that may represent a risk of material misstatement due to fraud. Management insights, estimates and assumptions that might have a major impact on the financial statements are disclosed in the notes to the financial statements. We performed a retrospective review of management judgments and assumptions related to significant accounting estimates reflected in prior year financial statements. Impairment testing of intangible and fixed assets is a significant area to our audit as the determination whether these assets are not carried at more than their recoverable amounts is subject to significant management judgment. Reference is made to the section 'Our key audit matters'.
- For significant transactions we evaluated whether the business rationale of the transactions suggests that they may have been entered into to engage in fraudulent financial reporting or to conceal misappropriation of assets.

Secondly, we identified a fraud risk with respect to cash disbursements and performed the following procedures:

- We have reconciled all recorded cash movements during the year to the opening and closing balances;
- We have performed an evaluation of bank authorization policies and based hereon we have evaluated cash disbursements per bank account;
- We have traced and agreed recorded cash disbursements to supporting documents.

This did not lead to indications for fraud potentially resulting in material misstatements.

### **Audit approach compliance with laws and regulations**

We assessed the laws and regulations relevant to the company through discussion with those charged with governance, reading minutes.

As a result of our risk assessment procedures, and while realizing that the effects from non-compliance could considerably vary, we considered the following laws and regulations: (corporate) tax law, the requirements under the International Financial Reporting Standards as adopted by the European Union (EU-IFRS) and Part 9 of Book 2 of the Dutch Civil Code with a direct effect on the financial statements as an integrated part of our audit procedures, to the extent material for the financial statements.

We obtained sufficient appropriate audit evidence regarding provisions of those laws and regulations generally recognized to have a direct effect on the financial statements.

Apart from these, NewAmsterdam Pharma Company N.V. is subject to other laws and regulations where the consequences of non-compliance could have a material effect on amounts and/or disclosures in the financial statements, for instance, through imposing fines or litigation.

Given the nature of NewAmsterdam Pharma Company N.V.'s business and the complexity of these other laws and regulations, there is a risk of non-compliance with the requirements of such laws and regulations.

Our procedures are more limited with respect to these laws and regulations that do not have a direct effect on the determination of the amounts and disclosures in the financial statements. Compliance with these laws and regulations may be fundamental to the operating aspects of the business, to NewAmsterdam Pharma Company N.V.'s ability to continue its business, or to avoid material penalties (e.g., compliance with the terms of operating licenses and permits or compliance with environmental regulations) and therefore non-compliance

with such laws and regulations may have a material effect on the financial statements. Our responsibility is limited to undertaking specified audit procedures to help identify non-compliance with those laws and regulations that may have a material effect on the financial statements. Our procedures are limited to (i) inquiry of management, the supervisory board, the executive board and others within NewAmsterdam Pharma Company N.V. as to whether NewAmsterdam Pharma Company N.V. is in compliance with such laws and regulations and (ii) inspecting correspondence, if any, with the relevant licensing or regulatory authorities to help identify non-compliance with those laws and regulations that may have a material effect on the financial statements.

Naturally, we remained alert to indications of (suspected) non-compliance throughout the audit.

Finally, we obtained written representations that all known instances of (suspected) fraud or non-compliance with laws and regulations have been disclosed to us.

### **Audit approach going concern**

As explained in Note 2 of the consolidated financial statements, the Management has performed its going concern assessment and has not identified any going concern risks. To assess the Management's assessment, we have performed, among other things, the following procedures:

- We considered whether management's assessment of the going concern risks includes all relevant information of which we are aware of as a result of our audit;
- We analyzed the company's financial and liquidity position as at year-end and compared it to the previous financial year as well as expected cash outflows in terms of indicators that could identify significant going concern risks;
- We compared the actual current financial year's operating loss and the related cash outflows results with the forecasted current financial year's operating loss and cash outflows.

The outcome of our risk assessment procedures did not give reason to perform additional audit procedures on management's going concern assessment.

### **Our key audit matters**

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements. We have communicated the key audit matters to The Board of Directors. The key audit matters are not a comprehensive reflection of all matters discussed.

We believe the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

### **Key Audit Matters**

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements of the current period. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

### **Research and development accruals and prepayments – Refer to Notes 2, 8 and 9 to the financial statements**

#### *Key Audit Matter Description*

As disclosed in Note 2 to the financial statements, the Company records research and development accruals and prepayments for clinical trials based on estimates of the progress to completion of specific research and development tasks using data including information provided by vendors on their actual costs incurred. For certain vendors involved in clinical trials, the actual progress of the research and development activities may significantly differ from timing and value of invoices received and/or payments remitted under the terms of the

agreements. Estimates of expenses incurred are further determined through discussions with both internal personnel and vendors as to the status of progress of completion of the specified research and development tasks. Expenses incurred in excess of amounts invoiced are recorded as accruals. Payments made in excess of expenses incurred are recorded as prepayments.

We identified the research and development accruals and prepayments of certain vendors in clinical trials as a key audit matter because of the significant judgement required by management in estimating the progress of the research and development activities conducted, as the progress is not directly observable. This required a high degree of auditor judgement and an increased extent of effort when performing procedures to audit management's estimates of progress and evaluating the results of those procedures.

#### ***How the Key Audit Matter Was Addressed in the Audit***

Our audit procedures related to the research and development accruals and prepayments included the following, among others:

- Evaluating the Company's process, methodology, and significant assumptions made in estimating the value of expenses incurred for which the invoice has not been received and the payments made for which underlying procedures had not been carried out.
- Testing the completeness and accuracy of the data underlying the measurement and recognition of the accruals and prepayments including sending direct confirmations with the vendors.
- Inspecting selected research agreements, as well as amendments thereto, to evaluate whether the progress of the clinical trials reflects all relevant contractual elements.
- Assessing publicly available information, such as press releases and investor presentations, and board's meeting minutes regarding the status of clinical trial activities and comparing this information to the judgments applied in recording of the accruals and prepayments.
- Performing retrospective analysis of accruals at the end of the prior period to current year activity for a selection of contracts to assess the accuracy of the Company's estimation methodology.

Performing inquiries with Company personnel outside of the finance department who are responsible for overseeing the activities performed by the Company's contracted third-party vendors, which include the vendor's estimate of the progress of a selection of clinical trials.

#### **Report on the other information included in the annual report**

The annual report contains other information, in addition to the financial statements and our auditor's report thereon.

The other information consists of:

- The Board Report.
- Other information as required by Part 9 of Book 2 of the Dutch Civil Code.

Based on the following procedures performed, we conclude that the other information:

- Is consistent with the financial statements and does not contain material misstatements.
- Contains all the information regarding the management report and the other information as required by Part 9 of Book 2 of the Dutch Civil Code.

We have read the other information. Based on our knowledge and understanding obtained through our audit of the financial statements or otherwise, we have considered whether the other information contains material misstatements.

By performing these procedures, we comply with the requirements of Part 9 of Book 2 of the Dutch Civil Code and the Dutch Standard 720. The scope of the procedures performed is substantially less than the scope of those performed in our audit of the financial statements.

Management is responsible for the preparation of the other information, including the Board 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.

## **Description of responsibilities regarding the financial statements**

### **Responsibilities of Management and the Board of Directors for the financial statements**

Management is responsible for the preparation and fair presentation of the financial statements in accordance with EU-IFRS and Part 9 of Book 2 of the Dutch Civil Code. Furthermore, management is responsible for such internal control as management determines is necessary to enable the preparation of the financial statements that are free from material misstatement, whether due to fraud or error.

As part of the preparation of the financial statements, management is responsible for assessing the company's ability to continue as a going concern. Based on the financial reporting frameworks mentioned, management should prepare the financial statements using the going concern basis of accounting unless management either intends to liquidate the company or to cease operations, or has no realistic alternative but to do so.

Management should disclose events and circumstances that may cast significant doubt on the company's ability to continue as a going concern in the financial statements.

The Board of Directors are responsible for overseeing the company's financial reporting process.

### **Our responsibilities for the audit of the financial statements**

Our objective is to plan and perform the audit engagement in a manner that allows us to obtain sufficient 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 misstatements, whether due to fraud or error, 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 judgment 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 are responsible for planning and performing the group audit to obtain sufficient appropriate audit evidence regarding the financial information of the entities or business units within the group as a basis for forming an opinion on the financial statements. We are also responsible for the direction, supervision and review of the audit work performed for purposes of the group audit. We bear the full responsibility for the auditor's report.

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.

From the matters communicated with The Board of Directors, we determine the key audit matters: those matters that were of most significance in the audit of the financial statements. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, not communicating the matter is in the public interest.

Eindhoven, 25 April 2025

Deloitte Accountants B.V.

A.J.M. Zwama-Bombeek

## **9.2 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.

## **9.3 Branches**

The Company has no branch offices.

## **9.4 Shares carrying limited economic entitlement**

There are currently no outstanding shares which carry a limited entitlement to the profits or reserves in the Company.

## 9.5 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 -<br>Notices applicable<br>to all medium-<br>sized and large<br>legal entities    | 1011 - 1014 | Business Policy                                                              | Section 2.1 | History and development<br>of the Company<br>Overview & strategy                      |
|                                                                                            |             |                                                                              | Section 2.2 |                                                                                       |
|                                                                                            | 1021        | Objective                                                                    | Section 2.2 | Overview & strategy                                                                   |
|                                                                                            |             |                                                                              | Section 2.3 | Operating results                                                                     |
|                                                                                            | 1031        | Corporate Structure                                                          | Section 2.1 | History and development<br>of the Company<br>Overview & strategy                      |
|                                                                                            |             |                                                                              | Section 2.2 |                                                                                       |
|                                                                                            | 1041-1042   | Financial<br>Developments                                                    | Section 2.3 | Operating results                                                                     |
|                                                                                            |             |                                                                              | Section 3   | Risks associated with our<br>business                                                 |
|                                                                                            | 1051-1058   | Risk Management                                                              | Section 3   | Risks associated with our<br>business                                                 |
|                                                                                            | 1061        | Culture and Behavior                                                         | Section 2.2 | Overview & strategy                                                                   |
|                                                                                            |             |                                                                              | Section 5.2 | Code of business conduct<br>and ethics and other<br>corporate governance<br>practices |
|                                                                                            |             |                                                                              | Section 5.7 | Diversity                                                                             |
|                                                                                            | 1071        | Risk Policy for<br>Financial Instruments                                     | Section 8.1 | Consolidated financial<br>statements                                                  |
| RJ 400.4<br>Additional<br>requirements<br>based on listed<br>shares or other<br>securities | 1081-1082   | Code of Conduct                                                              | Section 5.2 | Code of business conduct<br>and ethics and other<br>corporate governance<br>practices |
|                                                                                            | 1091-1095   | Research and<br>Development                                                  | Section 2.2 | Overview & strategy                                                                   |
|                                                                                            |             |                                                                              | Section 2.3 | Operating results                                                                     |
|                                                                                            | 1101-1106   | Future Prospects                                                             | Section 2.2 | Overview & strategy                                                                   |
|                                                                                            |             |                                                                              | Section 2.3 | Operating results                                                                     |
|                                                                                            | 1111        | Other Subjects                                                               | Section 2.2 | Overview & strategy                                                                   |
|                                                                                            |             |                                                                              | Section 2.3 | Operating results                                                                     |
|                                                                                            |             |                                                                              | Section 4   | Controls and procedures                                                               |
|                                                                                            | 4033        | Form of corporate<br>governance statement                                    | Section 4   | Controls and procedures                                                               |
|                                                                                            |             |                                                                              | Section 5   | Corporate governance                                                                  |
|                                                                                            |             |                                                                              | Section 5.7 | Diversity                                                                             |
|                                                                                            | 4044        | Notices on corporate<br>governance under the<br>corporate governance<br>code | Section 5   | Corporate governance                                                                  |

*Annual Financial Statements*

| <b>Source of requirement</b> | <b>Sub-section</b> | <b>Topic</b>      | <b>Location</b> |                                              |
|------------------------------|--------------------|-------------------|-----------------|----------------------------------------------|
| RJ 430                       |                    | Key figures       | Section 2.3     | Operating results                            |
|                              | 410.101            | Other information | Section 9       | Other information                            |
|                              | 410.102a           | Other information | Section 9.1     | Independent auditor's report                 |
| Article 2:392<br>DCC/RJ 410  | 410.102b           | Other information | Section 9.2     | Profit appropriation provisions              |
|                              | 410.102c           | Other information | Section 9.4     | Shares carrying limited economic entitlement |
|                              | 410.102f           | Other information | Section 9.3     | Branches                                     |

RJ = Guidelines on Annual Reporting (Richtlijnen voor de Jaarverslaggeving)

*Signature page to the NewAmsterdam Pharma Company N.V. 2024 financial statements*

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M.H. Davidson

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J.J.P. Kastelein

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J.N. Topper

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M. McKenna

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L. Lange

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N.S. Downing

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W. Joustra

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J.W. Smither

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H.J. van der Kamp

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W.H. Lewis

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A. Gulfo