UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

☒ **ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2024

OR

☐ **TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number 001-41562

NewAmsterdam Pharma Company N.V.

(Exact Name of Registrant as Specified in Its Charter)

The Netherlands	**N/A**
(State or Other Jurisdiction of Incorporation or Organization)	**(IRS Employer Identification No.)**

Gooimeer 2-35
1411 DC Naarden
The Netherlands
(Address of Principal Executive Offices)

+31 (0) 35 206 2971
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Ordinary shares, nominal value €0.12 per share	**NAMS**	**The Nasdaq Stock Market LLC**
Warrants to purchase ordinary shares	**NAMSW**	**The Nasdaq Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definition of "large accelerated filer," "accelerate filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated Filer	☑	Accelerated Filer	☐
Non- Accelerated Filer	☐	Smaller Reporting Company	☐
		Emerging Growth Company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☑

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☑

The aggregate market value of the registrant's ordinary shares held by non-affiliates was $1,051,390,348 as of June 30, 2024 (the last business day of the registrant's most recently completed second fiscal quarter), based on a total of 54,731,408 ordinary shares held by non-affiliates and a closing price of $19.21 as reported on the Nasdaq Global Market on June 30, 2024.

As of February 18, 2025, there were 109,817,812 of the registrant's ordinary shares, nominal value €0.12 per share, outstanding.

NewAmsterdam Pharma Company N.V.
ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2024

TABLE OF CONTENTS

		Page
PART I		
Item 1.	Business	7
Item 1A.	Risk Factors	42
Item 1B.	Unresolved Staff Comments	87
Item 1C.	Cybersecurity	87
Item 2.	Properties	88
Item 3.	Legal Proceedings	88
Item 4.	Mine Safety Disclosures	88
PART II		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	89
Item 6.	[Reserved]	89
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	90
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	98
Item 8.	Financial Statements and Supplementary Data	99
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosures	99
Item 9A.	Controls and Procedures	99
Item 9B.	Other Information	101
Item 9C	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	101
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	102
Item 11.	Executive Compensation	106
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	123
Item 13.	Certain Relationships and Related Transactions, and Director Independence	126
Item 14.	Principal Accountant Fees and Services	128
PART IV		
Item 15.	Exhibits and Financial Statement Schedules	129
Item 16.	Form 10-K Summary	130
	Signatures	131
	Financial Statements	F-1

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K ("Annual 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 the Company's 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 Annual Report include, but are not limited to, statements regarding the Company's disclosure concerning its operations, cash flows, financial position and dividend policy.

Forward-looking statements in this Annual Report and in any document incorporated by reference in this Annual 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 or on terms acceptable to it;
- the efficacy and safety of the Company's product candidate, obicetrapib, as well as potential reimbursement and anticipated market size and market opportunity;
- the Company's dependence on the success of obicetrapib, including the 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 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 the Company's 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 "*Risk Factors*" in this Annual Report. Accordingly, you should not place undue reliance 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, except as specifically required by law. You should, however, review the factors and risks that the Company describes in the reports it files 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. And 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.

SUMMARY OF SELECTED RISKS ASSOCIATED WITH OUR BUSINESS

Our business faces significant risks and uncertainties. If any of the following risks are realized, our business, financial condition and results of operations could be materially and adversely affected. You should carefully review and consider the full discussion of our risk factors in the section titled "*Risk Factors*" in Part I, Item 1A of this Annual Report. Some of the more significant risks include the following:

Risks Related to Our Limited Operating History, Financial Condition and Capital Requirements

- We are a clinical-stage company with limited operating history, no approved products and no historical product revenues, which makes it difficult to assess our future prospects and financial results. We have incurred net losses since our inception, and anticipate that we will continue to incur significant losses for the foreseeable future. We may never generate any product revenue or become profitable or, if we achieve profitability, may not be able to sustain it.
- We may require substantial additional financing to achieve our goals, and a failure to obtain this capital when needed and on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, commercialization efforts or other operations.

Risks Related to Our Product Development, Regulatory Approval and Commercialization

- We are dependent on the success of our only product candidate, obicetrapib, and cannot guarantee that obicetrapib will successfully complete clinical development, receive regulatory approval or, if approved, be successfully commercialized.
- Clinical drug development involves a lengthy and expensive process with uncertain outcomes. Results of earlier studies and trials may not be predictive of future trial results and our clinical trials may fail to adequately demonstrate the safety and efficacy of obicetrapib.
- The regulatory approval processes of the U.S. Food and Drug Administration (the "FDA"), the European Medicines Agency (the "EMA") and other comparable regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for obicetrapib, our business will be substantially harmed.
- Obicetrapib may produce undesirable side effects that we may not have detected in our previous preclinical studies and clinical trials. This could prevent us from gaining approval or market acceptance, including broad physician adoption, for our product candidate if approved, or from maintaining such approval and acceptance, and could substantially increase commercialization costs and even force us to cease operations.
- We are developing obicetrapib in combination with other therapies, and safety of supply issues with combination products may delay or prevent development and approval of our combination product candidate.
- Even if we receive regulatory approval for obicetrapib or our future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expenses, force us to limit or withdraw regulatory approval and subject us to penalties if we fail to comply with applicable regulatory requirements.
- Obicetrapib, if approved, will face significant competition from competing therapies and our failure to compete effectively may prevent us from achieving significant market penetration.
- We currently intend to rely on our collaboration with A. Menarini International Licensing S.A., part of Menarini Group ("Menarini") for the commercialization of obicetrapib, if approved, in certain European areas. Failure or delay of Menarini to fulfill all or part of its obligations to us under the exclusive license agreement , dated June 23, 2022, with Menarini (the "Menarini License"), a breakdown in collaboration between the parties or a complete or partial loss of this relationship could materially harm our business if obicetrapib is approved in the relevant jurisdictions.

Risks Related to Our Business and Strategy

- We have expanded and expect to continue expanding our development, regulatory and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.
- Our international operations subject us to various risks, and our failure to manage these risks could adversely affect our results of operations; we may also be exposed to significant foreign exchange risk.

Risks Related to Our Intellectual Property

- We may not be successful in obtaining all of the necessary intellectual property rights to allow us to develop and commercialize our product candidate, obicetrapib. If our efforts to obtain, protect or enforce our patents and other intellectual property rights related to our product candidates 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.

•Third-party claims alleging intellectual property infringement may adversely affect our business, and we may be subject to lawsuits claiming that we infringe, misappropriate or otherwise violate the intellectual property rights of third parties, which could be expensive and time consuming, delay or prevent the development and commercialization of our products and product candidates, or subject future sales to royalty payments, which could damage our business.

Risks Related to Ownership of Our Securities

•Sales of a substantial number of our securities in the public market by certain of our securityholders pursuant to a registration statement we filed and/or by our existing securityholders could cause the price of our Ordinary Shares and our warrants, each representing the right to purchase one Ordinary Share at an exercise price of $11.50, to fall.

•We no longer qualify as an "emerging growth company" as of December 31, 2024 and, as a result, we are no longer able to avail ourselves of certain reduced disclosure requirements applicable to emerging growth companies and therefore expect to incur increased expenses due to increased disclosure requirements.

PART I

Item 1. Business

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-hydroxycholestrol 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^2 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^2 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

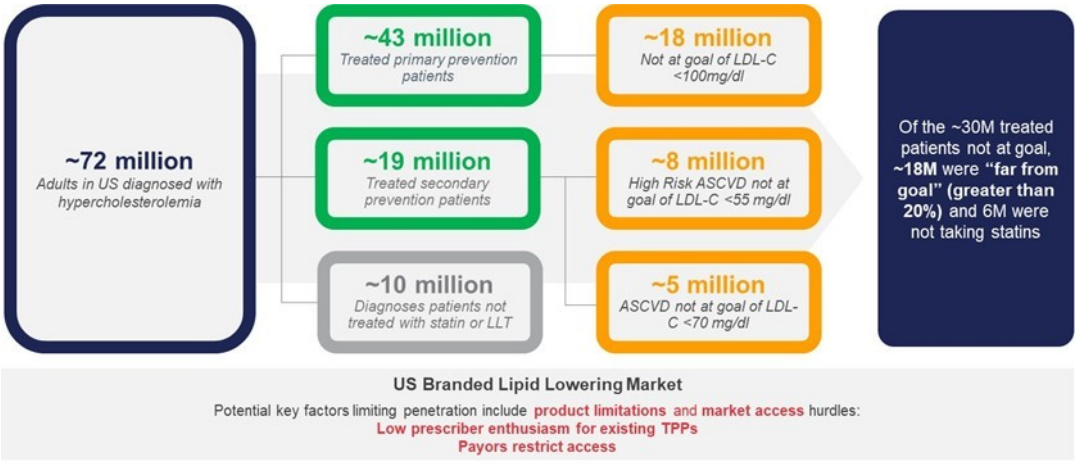
According to the World Health Organization, CVD is a leading cause of death globally and was responsible for approximately 19 million deaths, or approximately 32% of all global deaths, in 2020. Hyperlipidemia, more commonly known as high cholesterol, has been observed to nearly double the risk of developing 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, 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 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.

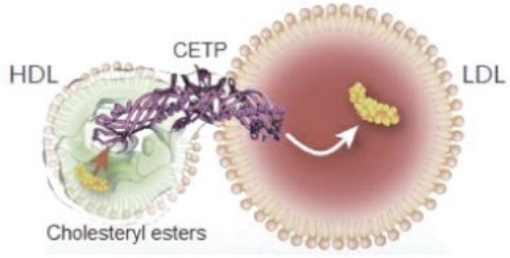
- ***Effect on other predictors of disease risk.*** Like other types of LDL-C lowering therapies, i.e., statins and PCSK9 inhibitors, CETP inhibition enhances the removal of ApoB, a protein found in lipoprotein particles that contributes to atherosclerosis. However, unlike statins, based on observations 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.

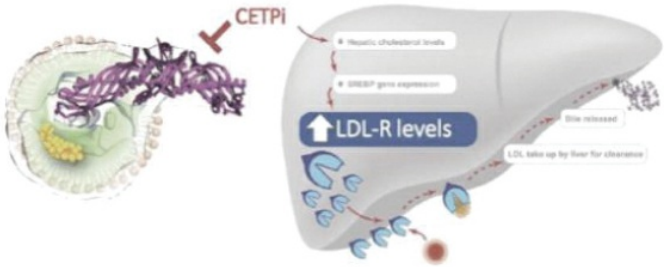
LDL-C and ApoB levels are mainly regulated by the liver through a surface protein known as the LDL receptor. Most current LDL-C lowering therapies work, at least in part, by increasing the number of LDL receptors, and thereby increasing the clearance of LDL particles from the blood. Statin therapy is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



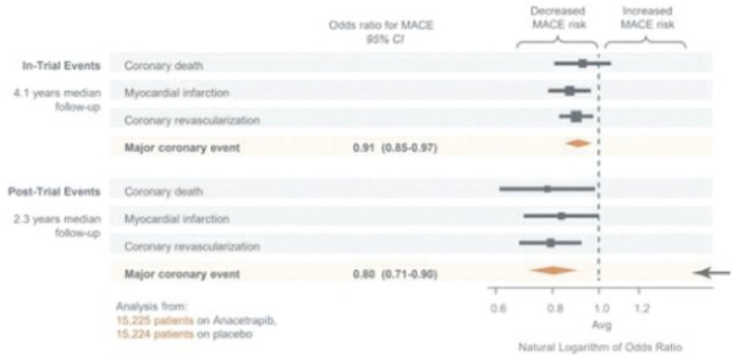
*Other than as noted, the pipeline represents trials that are currently ongoing. Projections are subject to inherent limitations. Actual results may differ from expectations. The timing of regulatory submissions is subject to additional discussions with regulators.

Obicetrapib for Cardiovascular Disease

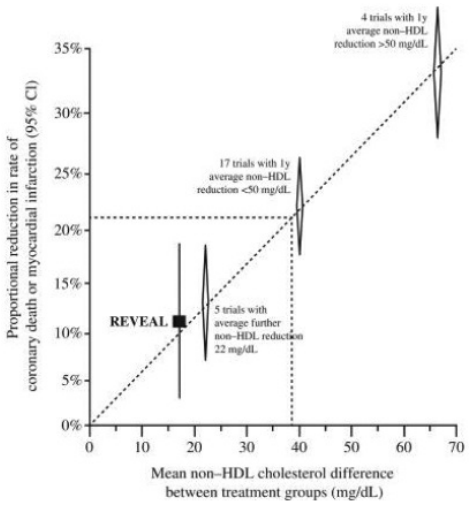
There is broad scientific consensus that elevation in LDL-C is a primary causal factor for ASCVD, and CVD outcomes in high-risk populations improve as the level of LDL-C achieved on therapy decreases. A study published in the Journal of the American Medicine in 2017 found that genetic variants related 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

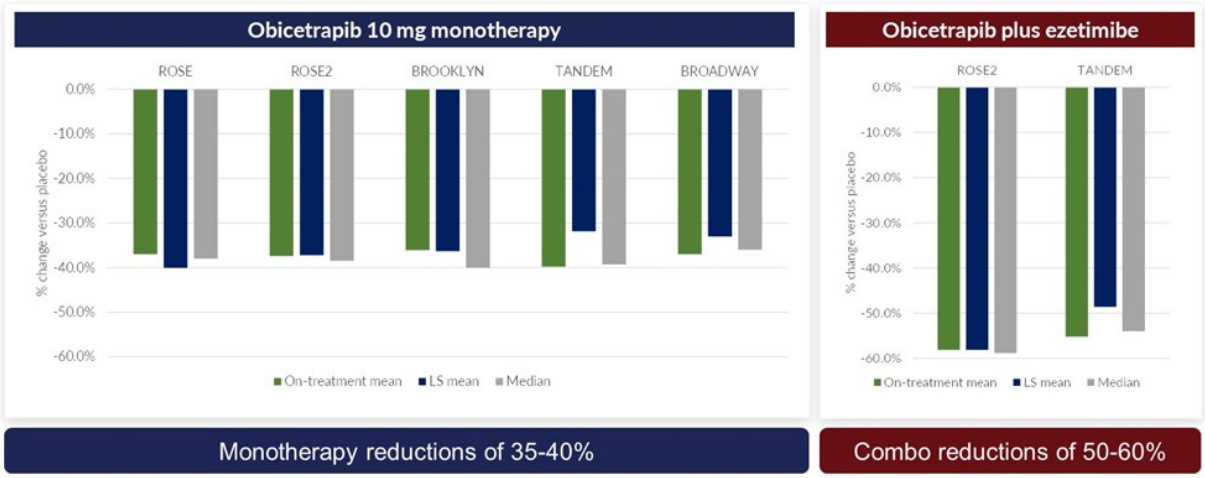
We have initiated REMBRANDT, a Phase 3 cardiovascular computed tomography angiography imaging trial to evaluate the effect of obicetrapib and ezetimibe in fixed-dose combination ("FDC") on coronary plaque. The placebo-controlled, double-blind, randomized, Phase 3 study is being conducted in adult participants 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 ≥ 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:

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

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 (n=118)	Obicetrapib (n=236)	Compared to Placebo	p-value
Day 84	+0.3%	-36.1%	-36.3%	<0.0001
Day 365	+10.3%	-31.1%	-41.5%	<0.0001

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

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

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 (n = 844)	**Obicetrapib 10 mg (n= 1686)**	**Hazard 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 (n = 962)	**Obicetrapib 10 mg (n= 1920)**	**Hazard Ratio**	**95% CI**
All-cause mortality – no. (%)	14 (1.5)	20 (1.0)	0.78	(0.39-1.58)

Coronary heart death – no. (%)	7 (0.7)	9 (0.5)	0.63	(0.24-1.70)
First 4-point MACE – no. (%)	49 (5.1)	75 (3.9)	0.75	(0.53-1.08)

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.

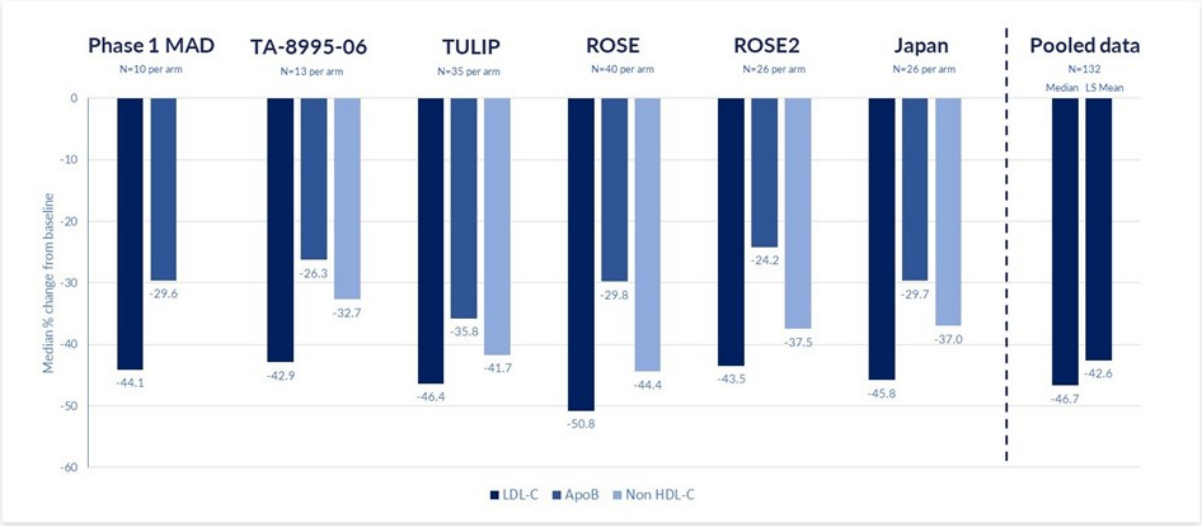
Neither the BROADWAY nor BROOKLYN trials were designed to assess MACE as the primary or secondary endpoints and as a result there are limitations on the results presented above. We are conducting PREVAIL, our Phase 3 cardiovascular outcomes trial designed to assess the MACE benefit of obicetrapib, to 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:

	Placebo N= 843 n (%)	**Obicetrapib 10 mg N= 1,685 n (%)**
Any TEAEs	513 (60.9)	1,007 (59.8)
Any TEAEs by maximum severity		
Mild	228 (27.0)	481 (28.5)
Moderate	217 (25.7)	408 (24.2)
Severe	68 (8.1)	118 (7.0)
Any trial drug related TEAEs	39 (4.6)	76 (4.5)
Any trial drug-related TEAEs by maximum severity		
Mild	25 (3.0)	51 (3.0)
Moderate	14 (1.7)	23 (1.4)
Severe	0 (0.0)	2 (0.1)
Any TEAEs leading to discontinuation of trial drug	43 (5.1)	68 (4.0)
Any TESAEs	117 (13.9)	211 (12.5)
Any treatment-emergent non-serious AEs	495 (58.7)	959 (56.9)
Any trial drug-related TESAEs	0 (0.0)	1 (0.1)
Any TEAEs leading to death	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 TESAE 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 TESAEs 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 ("Aβ") 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 Aβ 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 Aβ 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-hydroxycholestrol of 11% and 12%, respectively, in the CSF compared to baseline. In addition, an increase of 8% compared to baseline in the Aβ42/40 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 Aβ42/40 ratio and plasma pTau181, also believed to be biomarkers of Alzheimer's disease, with lower levels of Aβ42/40 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 ourselves 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 many only be conducted after obtaining approval of a CTA submitted to CDE, approval of the ethics committee at each accredited hospital site, and human genetic resource approval ("HGR"), which is required for the collection of samples and 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.

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.

Corporate Information

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, 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 (the "Domestication").

Upon the achievement of a certain clinical development milestone, we will issue to the Participating Shareholders (including Saga Investments Coöperatief U.A. ("Amgen"), an affiliate of Amgen, Inc., and Mitsubishi Tanabe Pharma Corporation ("MTPC") for this purpose) and holders of 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. As of December 31, 2024, 1,743,135 Earnout Shares and 143,002 Earnout Shares were 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 Closing Date.

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.

Available Information

Our website address is *www.newamsterdampharma.com*. Our website and information included in or linked to our website are not part of this Annual Report on Form 10-K. We file reports with the SEC, which we make available on our website free of charge. These reports include annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K 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 on Form 20-F and information furnished on Form 6-K filed while we were a foreign private issuer. In addition, the SEC maintains a website (www.sec.gov) that contains reports, proxy and information statements and other information regarding issuers, like us, that file electronically with the SEC.

Item 1A. Risk Factors

An investment in our Ordinary Shares is risky. In addition to the other information in this Annual Report on Form 10-K, you should carefully consider the following risk factors in evaluating us and our business. If any of the events described in the following risk factors were to occur, our business, financial condition, results of operation and future growth prospects would likely be materially and adversely affected. In that event, the trading price of our Ordinary Shares could decline, and you could lose all or a part of your investment in our Ordinary Shares. Therefore, we urge you to carefully review this entire report and consider the risk factors discussed below. Moreover, the risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business, financial condition, operating results or prospects. Additional risks that we currently do not know about, or that we currently believe to be immaterial, may also impair our business. Certain statements below are forward-looking statements. See "Special Note Regarding Forward-Looking Statements" in this Annual Report.

Risks Related to Our Limited Operating History, Financial Condition and Capital Requirements

We are a clinical-stage company with limited operating history, no approved products and no historical product revenues, which makes it difficult to assess our future prospects and financial results. We have incurred net losses since our inception, and anticipate that we will continue to incur significant losses for the foreseeable future. We may never generate any product revenue or become profitable or, if we achieve profitability, may not be able to sustain it.

We are a clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. Pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of uncertainty. Our operations to date have been limited to developing and undertaking clinical trials of our product candidate, obicetrapib. We are not profitable and have not generated product revenue from operations. We have historically incurred net losses since we commenced operations in October 2019. For the year ended December 31, 2024, we incurred a net loss of $241.6 million and as of December 31, 2024, we had an accumulated deficit of $558.6 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future, considering the current research and development stage of our activities, as we do not have products approved for commercial sale. Our ability to ultimately achieve recurring product revenues and profitability is dependent upon our ability to successfully complete the development of obicetrapib and obtain necessary regulatory approvals for, and successfully manufacture, market and commercialize, our product together with our partners.

We believe that we will continue to expend substantial resources in the foreseeable future for the clinical development of obicetrapib or any additional product candidates and indications that we may choose to pursue in the future. These expenditures will include costs associated with research and development, conducting preclinical studies and clinical trials, and payments for third-party manufacturing and supply, as well as sales and marketing of obicetrapib or any of our future product candidates if they are approved for sale by regulatory authorities. Because the outcome of any clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of obicetrapib and any other drug candidates that we may develop in the future. Other unanticipated costs may also arise.

Our future capital requirements depend on many factors, including:

•the timing of, and the costs involved in, clinical development and obtaining regulatory approvals for our product candidate;

•changes in regulatory requirements during the development phase that can delay or force us to stop our activities related to obicetrapib or any of our future product candidates;

•the cost of commercialization activities if obicetrapib is approved for sale, including marketing, sales and distribution costs;

•the cost of third-party manufacturing of our product candidate;

•the number and characteristics of any other product candidates we develop or acquire;

•our ability to establish and maintain strategic collaborations, licensing or other commercialization arrangements, and the terms and timing of such arrangements;

•the extent and rate of market acceptance of any future approved products;

•the expenses needed to attract and retain skilled personnel;

•the costs associated with being a public company, including additional costs associated with no longer qualifying as an emerging growth company;

•the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including potential litigation costs and the outcome of such litigation;

•the timing, receipt and amount of sales of, or royalties on, future approved products, if any;

•any product liability or other lawsuits related to obicetrapib or any future product;

•scientific breakthroughs in the field of treatment for cardiometabolic diseases that could significantly diminish the need for our product candidate or make it obsolete; and

•changes in reimbursement policies that could have a negative impact on our future revenue stream.

We may require substantial additional financing to achieve our goals, and a failure to obtain this capital when needed and on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, commercialization efforts or other operations.

Since our inception, almost all of our resources have been dedicated to the clinical development of obicetrapib. While we have been successful in the past in obtaining financing, we expect to continue to spend substantial amounts to continue the clinical development of our product candidate and on commercial readiness and establishment of sufficient commercial manufacturing capacity. As of December 31, 2024, we had cash and cash equivalents of $771.7 million.

We may require additional capital to pursue clinical activities, complete clinical trials, and obtain regulatory approval for and commercialize obicetrapib. In addition, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity, convertible debt or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or a combination of these approaches. Even if we believe that we will have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

Any additional fundraising efforts may divert the attention of our management from day-to-day activities, which may adversely affect our ability to develop and commercialize obicetrapib. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may negatively impact the holdings or the rights of our shareholders, and the issuance of additional securities, whether equity or debt, by us or the possibility of such issuance may cause the market price of our Ordinary Shares to decline. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

If adequate funds are not available to us on a timely basis, we may be required or choose to:

•delay, limit, reduce or terminate clinical trials or other development activities for obicetrapib or any of our future product candidates;

•delay, limit, reduce or terminate our other research and development activities; or

•delay, limit, reduce or terminate our establishment or expansion of manufacturing, sales and marketing or distribution capabilities or other activities that may be necessary to commercialize obicetrapib or any of our future product candidates.

We may also be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could harm our business, financial condition and results of operations.

Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or current or future product candidates.

Unless and until we can generate substantial revenue, we expect to finance our future cash needs through public or private equity offerings, debt financings, collaborations, strategic alliances, license agreements and marketing or distribution arrangements. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. To the extent that we raise such additional capital through the sale of equity or convertible debt securities, our shareholders' ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect the rights of our existing shareholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring and distributing dividends, and may be secured by all or a portion of our assets.

If we raise funds by entering into collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish additional valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us, any of which may harm our business, financial condition, operating results and prospects. If we are unable to raise additional funds through public or private equity offerings, debt financings, collaborations, strategic alliances, license agreements, or marketing or distribution arrangements when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or cease operations altogether.

We currently, and may in the future, have assets held at financial institutions that may exceed the insurance coverage offered by the Federal Deposit Insurance Corporation ("FDIC") and the Dutch Deposit Guarantee Scheme, the loss of which would have a severe negative affect on our operations and liquidity.

We currently maintain substantially all of our funds in cash deposit accounts at three financial institutions. The amounts held in our deposit accounts are, and in the future, may be, in excess of the insurance limit of $250,000 and €100,000 provided by the FDIC and Dutch

Deposit Guarantee Scheme, respectively. In the event of a failure of any of these financial institutions where we maintain our deposits or other assets, we may incur a loss to the extent such loss exceeds such limitations, which could have a material adverse effect upon our liquidity, financial condition and our results of operations.

Risks Related to Our Product Development, Regulatory Approval and Commercialization

We are dependent on the success of our only product candidate, obicetrapib, and cannot guarantee that obicetrapib will successfully complete clinical development, receive regulatory approval or, if approved, be successfully commercialized.

We have invested almost all of our efforts and financial resources in the research and development of obicetrapib. Our future success, including our ability to generate revenue, depends on our 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. We currently generate no revenue from the sale of any products, and we may never be able to develop or commercialize a marketable product.

Obicetrapib's marketability and commercialization are subject to significant risks associated with successfully completing current and future clinical trials, including:

- our ability to successfully complete our clinical trials, including timely patient enrollment and acceptable safety and efficacy data and our ability to demonstrate the safety and efficacy of obicetrapib;
- unless we have received a deferral or waiver, our ability to complete successfully any pediatric clinical trials agreed pursuant to the PREA or its EU equivalent;
- that the Phase 3 clinical trials, even if successfully completed, will be sufficient to support an NDA submission;
- the prevalence and severity of AEs associated with obicetrapib;
- whether we are required by the FDA, the EMA or other comparable regulatory authorities to conduct additional preclinical studies or clinical trials, and the scope and nature of such studies or trials, prior to approval to market our product, such as a cardiovascular outcomes trial;
- the timely receipt of necessary marketing approvals from the FDA, the EMA and other comparable regulatory authorities, including pricing and reimbursement determinations;
- the ability to successfully commercialize obicetrapib, if approved, for marketing and sale by the FDA, the EMA or other comparable regulatory authorities;
- our ability and the ability of our third-party manufacturing partners to timely and satisfactorily manufacture quantities of obicetrapib at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability;
- our success in educating healthcare providers and patients about the benefits, risks, administration and use of obicetrapib, if approved;
- acceptance of obicetrapib, if approved, as safe and effective by patients and the healthcare community;
- the maintenance of an acceptable safety profile of our product following any approval;
- the availability, perceived advantages, relative cost, safety and efficacy of alternative and competing treatments for the indications addressed by obicetrapib;
- entering into, on favorable terms, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize obicetrapib;
- the effectiveness of our and any current or future collaborators' marketing, sales and distribution strategy, and operations;
- our ability to obtain, protect and enforce our intellectual property rights with respect to obicetrapib; and
- our ability to implement strategies to minimize the impact of pandemics or other health epidemics to our business, including with respect to initiating, enrolling, conducting or completing our planned and ongoing clinical trials of obicetrapib and addressing any potential disruption or delays to the supply of our product candidates.

Many of these clinical, regulatory and commercial risks are beyond our control. Accordingly, we cannot assure you that we will be able to advance obicetrapib successfully through clinical development, or to obtain regulatory approval of, or commercialize, obicetrapib or any future product candidates. If we fail to achieve these objectives or overcome the challenges presented above, we could experience significant delays or an inability to successfully commercialize obicetrapib. Accordingly, we may not be able to generate sufficient revenues through the sale of obicetrapib to enable us to continue our business.

We have never obtained approval for, or commercialized, any product candidate, and may be unable to do so successfully.

As a company, we have never progressed a product candidate through to regulatory approval. We have not previously submitted an NDA, an MAA or any similar drug approval filing to the FDA, the EMA or any comparable regulatory authority for any product candidate, and we cannot be certain that obicetrapib will be successful in clinical trials or receive regulatory approval. Further, obicetrapib may not receive regulatory approval even if it is successful in clinical trials. Even if we successfully obtain regulatory approvals to market our product candidate, our revenues will be dependent, to a significant extent, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights or share in revenues from the exercise of such rights. If the markets for patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved. In addition, there are, in general, relatively limited sources that can provide commercial product supply. While we believe our existing suppliers are sufficient to support our estimated target commercial market, and that alternative sources of supply exist if needed, there is no guarantee that our current and projected supply would be sufficient to support our commercials needs, if approved, especially if the market for obicetrapib is larger than we expected.

Further, our clinical trials may require more time and incur greater costs than we anticipate. We cannot be certain that our planned clinical trials will begin or conclude on time, if at all. Large-scale trials require significant financial and management resources. Third-party clinical investigators do not operate under our control. Any performance failure on the part of such third parties could delay the clinical development of obicetrapib or delay or prevent us from obtaining regulatory approval or commercializing obicetrapib or future product candidates, depriving us of potential product revenue and resulting in additional losses.

Clinical drug development involves a lengthy and expensive process with uncertain outcomes. Results of earlier studies and trials may not be predictive of future trial results and our clinical trials may fail to adequately demonstrate the safety and efficacy of obicetrapib.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Trial costs have increased significantly following the COVID-19 pandemic. A failure of one or more of our clinical trials can occur at any time during the clinical trial process. We do not know whether future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. Clinical trials can be delayed, suspended or terminated for a variety of reasons, including failure to:

- obtain allowance from the FDA or comparable foreign regulatory authorities in order to commence a trial;
- identify, recruit and train suitable clinical investigators;
- reach agreement on acceptable terms with prospective contract research organizations ("CROs"), and clinical trial sites, and have such CROs and sites effect the proper and timely conduct of our clinical trials;
- obtain and maintain IRB approval, or comparable EC approval in foreign jurisdictions, at each clinical trial site;
- identify, recruit and enroll suitable patients to participate in a trial;
- have a sufficient number of patients complete a trial or return for post-treatment follow-up;
- ensure patient compliance with the trial protocols;
- ensure clinical investigators and clinical trial sites observe trial protocol or continue to participate in a trial;
- address any patient safety concerns that arise during the course of a trial;
- address any conflicts with new or existing laws or regulations;
- add a sufficient number of clinical trial sites;
- manufacture sufficient quantities at the required quality of obicetrapib for use in clinical trials;
- obtain accurate and complete data collected by our clinical trial sites;
- retain a sufficient number of subjects to complete our clinical trials; or
- raise sufficient capital to fund a trial.

Product candidates like obicetrapib in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and earlier clinical trials, especially given the large number of patients enrolled and the extended timeline to complete such trials, including late-stage CVOT trials. 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. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials, and it is possible that we will as well. Based upon negative or inconclusive results, including with respect to our ongoing Phase 3 PREVAIL trial, we may decide, or regulators may require us, to conduct

additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval.

We may also encounter delays if a clinical trial is suspended or terminated by us or the IRBs or ECs of the institutions in which such trials are being conducted, the trial's data safety monitoring board (the "DSMB"), the FDA, the EMA or other comparable regulatory authorities. Such authorities may suspend or terminate one or more of our clinical trials due to a number of factors, including our failure to conduct the clinical trial in accordance with relevant regulatory requirements or clinical protocols, inspection of the clinical trial operations or trial site by the FDA, the EMA or other comparable regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, a finding that the participants are being exposed to an unacceptable benefit-risk ratio, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we experience delays in the initiation, enrollment or completion of any clinical trial of obicetrapib, or if any clinical trials of obicetrapib are cancelled or fail to adequately demonstrate the safety and efficacy of obicetrapib, the commercial prospects of obicetrapib may be materially adversely affected, and our ability to generate product revenues will be delayed or not realized at all. In addition, any delays in completing our clinical trials may increase our costs and slow down our product candidate development and approval process. Any of these delays may significantly harm our business and financial condition. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of obicetrapib.

We depend on enrollment and retention of subjects in our clinical trials for obicetrapib. If we experience delays or difficulties enrolling or retaining subjects in our clinical trials, our research and development efforts and business, financial condition and results of operations could be materially adversely affected.

If we experience delays or difficulties in the enrollment and retention of subjects in our ongoing or future clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented. The enrollment of subjects depends on many additional factors, including:

- the subject eligibility criteria defined in the protocol;
- the general willingness of subjects to enroll in the trial;
- patient compliance with the trial protocols;
- the sample size of the subjects required for analysis of the trial's primary endpoints;
- the proximity of subjects to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and subjects' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new therapies that may be approved for the indications we are investigating;
- the clinical site's ability to obtain and maintain subject consents; and
- clinical trial participants may not comply with clinical trial protocol procedures and instructions.

Our clinical trials may also compete with other clinical trials for product candidates that seek to treat cardiometabolic diseases, and this competition will reduce the number and types of subjects available to us. In addition, our clinical trials, in particular the Phase 3 CVOT PREVAIL trial, are being conducted over the course of several years, during which new clinical trials by our competitors may be initiated. Even if we are able to enroll a sufficient number of subjects in our clinical trials, such subjects may later opt to enroll in a clinical trial that is initiated by one of our competitors. The number of subjects available for our clinical trials at certain clinical trial sites may also be reduced due to the limited number of qualified clinical investigators, which may lead us to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use.

Delays in subject enrollment and difficulties in subject retention may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of obicetrapib.

Interim, "topline" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we have disclosed and in the future may publicly disclose preliminary or "topline" data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or clinical trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the "topline" or preliminary results that we report may differ from future results of the same studies, or different conclusions or

considerations may qualify such results, once additional data have been received and fully evaluated. "Topline" data also remain subject to audit and verification procedures that may result in the final data being materially different from the data we previously published. As a result, "topline" data should be viewed with caution until the final data are available.

Additionally, we have disclosed and in the future may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our Ordinary Shares.

Further, others, including regulatory authorities and collaboration or regional partners, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of our particular program, the approvability or commercialization of obicetrapib or any future product candidate and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, "topline," or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, obicetrapib may be harmed, which could significantly harm our business, financial condition, results of operations and prospects.

The regulatory approval processes of the FDA, the EMA and other comparable regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for obicetrapib, our business will be substantially harmed.

The research, development, testing, manufacturing, labeling, packaging, approval, promotion, advertising, storage, recordkeeping, marketing, distribution, post-approval monitoring and reporting, and export and import of drug products are subject to extensive regulation by the FDA, the EMA and other comparable regulatory authorities in other countries. These regulations differ from country to country. We have not yet obtained regulatory approval to market obicetrapib in the United States or any other country, but plan to seek approval of obicetrapib in the United States, the EU, the United Kingdom, Japan and China. To gain approval to market obicetrapib, we must provide clinical trial data that adequately demonstrate the safety and efficacy of the product for the intended indication.

We cannot be certain of the timely completion or outcome of any of our current and future clinical studies, if any, on obicetrapib. We cannot be sure that the FDA, local regulatory authorities in the EU or other comparable regulatory authorities (including the Medicines and Healthcare products Regulatory Agency in the United Kingdom ("MHRA"), the PMDA and the NMPA) will accept the outcome of our clinical trial data as sufficient to support the submission of an IND, clinical trial authorizations ("CTAs") or similar applications for any of our programs which may result in us being unable to submit INDs, CTAs or similar applications or result in FDA, local regulatory authorities in the EU or other comparable regulatory authority refusing to allow clinical trials to begin. Furthermore, Phase 3 clinical trials often produce unsatisfactory results even though prior clinical trials were successful. Moreover, the results of clinical trials may be unsatisfactory to the FDA, the EMA, the MHRA, the PMDA, the NMPA or other comparable regulatory authorities even if we believe those clinical trials to be successful. The FDA, the EMA, the MHRA, the PMDA, the NMPA or other comparable regulatory authorities may suspend one or all of our clinical trials or require that we conduct additional clinical, preclinical, manufacturing, validation or drug product quality studies and submit that data before considering or reconsidering any NDA or comparable foreign regulatory application that we may submit. Depending on the extent of these additional studies, approval of any applications that we submit may be significantly delayed or may cause the termination of such programs, or may require us to expend more resources than we have available. The FDA, the EMA, the MHRA, the PMDA, the NMPA or other comparable regulatory authorities can delay, limit or deny approval of our product candidate for many reasons, including:

- our inability to satisfactorily demonstrate that obicetrapib is safe and effective for the target indication;
- the FDA, the EMA, the MHRA, the PMDA, the NMPA or other comparable regulatory authorities may disagree with our clinical trial protocol, the interpretation of data from preclinical studies or clinical trials, or adequate conduct and control of clinical trials;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, the EMA, the MHRA, the PMDA, the NMPA or other comparable regulatory authorities for approval;
- the population studied in the clinical trials may not be sufficiently broad or representative to assess safety in the patient population for which we seek approval;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, the EMA, the MHRA, the PMDA, the NMPA or other comparable regulatory authorities for approval;
- our inability to demonstrate that clinical or other benefits of obicetrapib outweigh any safety or other perceived risks;

•determination by the FDA, the EMA, the MHRA, the PMDA, the NMPA or other comparable regulatory authorities that additional preclinical studies or clinical trials are required or that additional data must be included;

•the FDA, the EMA, the MHRA, the PMDA, the NMPA or other comparable regulatory authorities may fail to approve of the formulation, labeling or the specifications of obicetrapib;

•the FDA, the EMA, the MHRA, the PMDA, the NMPA or other comparable regulatory authorities may fail to accept the manufacturing processes or facilities of third-party manufacturers with which we contract;

•the FDA, the EMA, the MHRA, the PMDA, the NMPA or other comparable regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies or such processes or facilities may not pass a pre-approval inspection;

•the potential for approval policies or regulations of the FDA, the EMA, the MHRA, the PMDA, the NMPA or other comparable regulatory authorities to significantly change or differ from another in a manner rendering our clinical data insufficient for approval; or

•resistance to approval from the FDA's advisory committee for any reason including safety or efficacy concerns.

The FDA, the EMA or other comparable regulatory authorities may also approve obicetrapib for a more limited indication or a narrower patient population than we originally requested, and the FDA, the EMA or other comparable regulatory authorities may not approve the labeling that we believe is necessary or desirable for the successful commercialization of obicetrapib. To the extent we seek regulatory approval in other foreign countries, we may face challenges similar to those described above with regulatory authorities in applicable jurisdictions.

We and our collaborator(s) are not permitted to market or promote obicetrapib before we receive regulatory approval from the FDA, the EMA, the MHRA, the PMDA, the NMPA or comparable regulatory authorities in other countries, and we may never receive such regulatory approval for obicetrapib to allow us to successfully commercialize our product candidate. If we do not receive regulatory approval with the necessary conditions to allow successful commercialization, we will not be able to generate revenue from obicetrapib in the United States or other countries in the foreseeable future, or at all. Any delay in obtaining, or inability to obtain, applicable regulatory approval for obicetrapib would delay or prevent commercialization of our obicetrapib and could thus negatively impact our business, results of operations and prospects.

Our ongoing clinical trials may be subject to delays or failures, which could result in increased costs to us and could delay, prevent or limit our ability to obtain regulatory approval for obicetrapib, which could have an adverse impact on our business.

In addition to our Phase 3 lipid-lowering clinical trials for obicetrapib, we are currently conducting a CVOT, in patients with ASCVD. The completion of these clinical trials or any of our other ongoing or future clinical trials may be delayed for a number of reasons, including:

•the FDA, EMA or any other regulatory authority may not agree with the clinical trial design or overall program;

•the FDA, EMA or any other regulatory authority may place a clinical trial on hold;

•delays in reaching or failing to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;

•inadequate quantity or quality of a product candidate or other materials necessary to conduct clinical trials;

•difficulties or delays obtaining IRB or EC approval to conduct a clinical trial at a prospective site or sites;

•severe or unexpected drug-related side effects experienced by patients in a clinical trial, including instances of muscle pain or weakness or other side effects;

•reports from preclinical or clinical testing of other cardiometabolic therapies that raise safety or efficacy concerns; and

•difficulties retaining patients who have enrolled in a clinical trial but may be prone to withdraw due to rigors of the clinical trial, lack of efficacy, side effects, personal issues or loss of interest.

In addition, a clinical trial may be suspended or terminated by us, the FDA, the EMA, the IRBs or ECs at the sites where the IRBs or ECs are overseeing a clinical trial, a DSMB overseeing the clinical trial at issue or any other regulatory authorities due to a number of factors, including, among others:

•failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

•inspection of the clinical trial operations or clinical trial sites by the FDA, EMA or any other regulatory authorities that reveals deficiencies or violations that require us to undertake corrective action, including the imposition of a clinical hold;

•unforeseen safety issues;

•changes in government regulations or administrative actions;

•problems with clinical supply materials; and

•lack of adequate funding to continue the clinical trial.

Any such delays in our clinical trials could result in increased costs to us and delay, prevent or limit our ability to obtain regulatory approvals. Significant nonclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may materially harm our business and results of operations.

Obicetrapib may produce undesirable side effects that we may not have detected in our previous preclinical studies and clinical trials. This could prevent us from gaining approval or market acceptance, including broad physician adoption, for our product candidate, if approved, or from maintaining such approval and acceptance, and could substantially increase commercialization costs and even force us to cease operations.

As with most pharmaceutical products, use of obicetrapib may be associated with side effects or AEs that can vary in severity and frequency. Side effects or AEs associated with the use of obicetrapib may be observed at any time, including in clinical trials or once a product is commercialized, and any such side effects or AEs may negatively affect our ability to obtain regulatory approval or market obicetrapib. We cannot assure you that we will not observe drug-related serious AEs in the future or that the FDA, the EMA, the MHRA, the PMDA, the NMPA or other comparable regulatory authorities will not determine them to be as such. Side effects such as toxicity or other safety issues associated with the use of obicetrapib could require us to perform additional trials or halt development or sale of obicetrapib or expose us to product liability lawsuits, which will harm our business.

Furthermore, our current Phase 3 clinical trials for obicetrapib, especially our PREVAIL CVOT, involve a larger patient base than that previously studied, and the commercial marketing of obicetrapib, if approved, will further expand the clinical exposure of the drug to a wider and more diverse group of patients than those participating in the clinical trials, which may identify undesirable side effects caused by our product candidate that were not previously observed or reported.

We may fail to report AEs that the FDA, the EMA and other comparable regulatory authority regulations require that we report certain information about adverse medical events if our product may have caused or contributed to those AEs. The timing of our obligation to report would be triggered by the date upon which we become aware of the AE as well as the nature and severity of the event. We may also fail to appreciate that we have become aware of a reportable AE, especially if it is not reported to us as an AE or if it is an AE that is unexpected or removed in time from the use of our product. If we fail to comply with our reporting obligations, the FDA, the EMA, the MHRA, the PMDA, the NMPA or other comparable regulatory authority could take action including enforcing a hold on or cessation of clinical trials, withdrawal of approved drugs from the market, criminal prosecution, the imposition of civil monetary penalties or seizure of our product.

Additionally, in the event we discover the existence of adverse medical events or side effects caused by obicetrapib, a number of other potentially significant negative consequences could result, including:

•our inability to file an NDA or similar application for obicetrapib because of insufficient benefit-risk profile, or the denial of such application by the FDA, the EMA or other comparable regulatory authorities;

•the FDA, the EMA or other comparable regulatory authorities suspending or withdrawing their approval of the product;

•the FDA, the EMA or other comparable regulatory authorities requiring the addition of labeling statements, such as warnings or contraindications or distribution and use restrictions;

•the FDA, the EMA or other comparable regulatory authorities requiring us to issue specific communications to healthcare professionals, such as letters alerting them to new safety information about our product, changes in dosage or other important information;

•the FDA, the EMA or other comparable regulatory authorities issuing negative publicity regarding the affected product, including safety communications;

•our being limited with respect to the safety-related claims that we can make in our marketing or promotional materials;

•our being required to change the way the product is administered, conduct additional preclinical studies or clinical trials, or restrict or cease the distribution or use of the product; and

•our being sued and held liable for harm caused to patients.

Any of these events could prevent us from achieving approval or market acceptance of obicetrapib and could substantially increase commercialization costs or even force us to cease operations. We cannot assure you that we will resolve any issues related to any product-related AEs to the satisfaction of the FDA, the EMA or other comparable regulatory authority in a timely manner or ever, which could harm our business, prospects and financial condition.

We conduct clinical trials for our product candidate outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials, in which case our development plans in the United States and applicable foreign jurisdictions may be delayed, which could materially harm our business.

Our ongoing clinical trials are being conducted both within and outside the United States, and we intend to conduct portions of our future clinical trials outside the United States. The acceptance of clinical trial data by the FDA, EMA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions, or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In cases where data from foreign clinical trials are intended to serve as the basis for marketing authorizations in the EU, the EMA and/or local regulatory authorities in EU member states require that such clinical trials follow the principles that are equivalent to the clinical trial requirements set out under relevant EU legislation, including with respect to ethical and GCP standards. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that any U.S. or foreign regulatory authority would accept data from clinical trials conducted outside of its applicable jurisdiction. If the FDA, EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional clinical trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

Disruptions at the FDA and other regulatory agencies caused by funding shortages or future global health crises could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and clear or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new products or modifications to be approved by government agencies, which would adversely affect our business. Over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory authorities, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process its regulatory submissions or provide feedback with respect to our planned clinical trials, which could have a material adverse effect on our business.

If a prolonged government shutdown occurs, or if global health crises prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

In addition, the new presidential administration has indicated that it may pursue significant changes to the operation of the FDA and other agencies, including significantly reducing the size of the workforce at the FDA. The effect of these changes, if adopted, is not clear at this time. There is a risk that the changes will disrupt the functioning of the FDA in ways that effect the review of our submissions.

Even if we receive regulatory approval for obicetrapib or our future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expenses, limit or withdraw regulatory approval and subject us to penalties if we fail to comply with applicable regulatory requirements.

Any regulatory approvals that we receive for obicetrapib or future product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, risk mitigation and surveillance to monitor the safety and efficacy of the product candidate, and we may be required to include labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings. Such requirements could negatively impact us by reducing revenues or increasing expenses, and cause the approved product not to be commercially viable. Absence of long-term safety data may further limit the approved uses of our product, if any.

If the FDA, the EMA or other comparable regulatory authority approves obicetrapib, the manufacturing processes, labeling, packaging, distribution, AE reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration requirements and continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. For certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States. The EU similarly has in force falsified medicines rules, which require appropriate packaging, labeling, registration and tracking of certain medicinal products to ensure the

detection of counterfeit medicinal products, and associated reporting requirements. Later discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- suspension or imposition of restrictions on operations, including costly new manufacturing requirements;
- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary product recalls;
- fines, untitled or warning letters or holds on clinical trials;
- refusal by the FDA, the EMA or other comparable regulatory authority to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates the promotional claims that may be made about drug products. In particular, the FDA prohibits the pre-approval promotion of drugs as safe and effective for the purposes for which they are under investigation. Similarly, the FDA prohibits the promotion of approved drugs for new or unapproved indications. Comparable restrictions apply in the EU, where, in addition, the advertising of prescription only medications to the general public is prohibited . If we are found to have improperly engaged in pre-approval promotion or to have improperly promoted off-label uses of our product candidates, we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions, which would materially adversely affect our business and financial condition. The FDA could issue a public untitled or warning letter to us. We could also be subject to FDA prohibition on the sale or marketing of our product candidates or significant fines and penalties. The imposition of these sanctions could affect our reputation and position within the industry. Additionally, if the FDA believes we have improperly promoted an investigational product pre-approval, it is possible that it could lead the FDA to be more strict in their review of our application, including our proposed labeling for a drug.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize obicetrapib, and harm our business, financial condition and results of operations.

In addition, the policies of the FDA, the EMA, the MHRA, the PMDA, the NMPA and other comparable regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of obicetrapib. Costs arising out of any regulatory developments could be time-consuming and expensive and could divert management resources and attention and, consequently, could adversely affect our business, financial condition and results of operations. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

The FDA, the EMA or other comparable regulatory authorities strictly regulate the promotional claims that may be made about prescription drug products, such as obicetrapib, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA, the EMA or other comparable regulatory authorities as reflected in the product's approved labeling. For example, if we receive marketing approval for obicetrapib for cardiometabolic disease, physicians, in their professional medical judgment, may nevertheless prescribe obicetrapib to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label use, we may become subject to significant liability under the FDCA and other statutory authorities, such as laws prohibiting false claims for reimbursement. The federal government in the United States has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred and our reputation could be damaged. The U.S. government has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to prohibitions on the sale or marketing of our products or significant fines and penalties, and the imposition of these sanctions could also affect our reputation with physicians, patients and caregivers, and our position within the industry.

We are developing obicetrapib in combination with other therapies, and safety or supply issues with combination products may delay or prevent development and approval of our combination product candidate.

We are developing obicetrapib as both a monotherapy and in combination with one or more approved therapies. For example, we are evaluating obicetrapib in combination with ezetimibe, including the combination on top of high intensity statin therapy. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, the EMA, the MHRA, the PMDA, the NMPA or other comparable regulatory authorities could revoke approval of the therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with

any of those existing therapies. If the therapies we use in combination with our product candidate are replaced as the standard of care for the indications we choose for any of our product candidate, the FDA, the EMA, the MHRA, the PMDA, the NMPA or other comparable regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own product, if approved, being removed from the market or being less successful commercially.

We also may evaluate our product candidate or any future product candidates in combination with one or more therapies that have not yet been approved for marketing by the FDA, the EMA, the MHRA, the PMDA, the NMPA or other comparable regulatory authorities. We will not be able to market and sell any product candidate we develop in combination with an unapproved therapy if that unapproved therapy does not ultimately obtain marketing approval. In addition, unapproved therapies face the same risks described with respect to our product candidate currently in development, including the potential for serious adverse effects, lack of efficacy, delay in their clinical trials and lack of FDA, EMA, MHRA, PMDA or NMPA approval.

If the FDA, the EMA, the MHRA, the PMDA, the NMPA or other comparable regulatory authorities do not approve these other therapies or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the therapies we choose to evaluate in combination with our product candidates, we may be unable to obtain approval of or market any such product candidate.

If we are not successful in our efforts to discover, in-license or acquire and develop additional product candidates, we may be unable to grow our business.

We may elect to build a pipeline of product candidates and progress these product candidates through clinical development for the treatment of a variety of diseases. We also intend to evaluate additional potential indications for obicetrapib and may choose to in-license or acquire other product candidates or commercial products to treat patients suffering from other cardiometabolic or other diseases with significant unmet medical needs. Efforts to identify, in-license or acquire, and develop or continue to develop, product candidates require substantial technical, financial and human resources, whether or not any such product candidates are ultimately advanced. Even if we are successful in building our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects, lack of efficacy, or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. Further, in-licensing early-stage product candidates can be particularly risky as it requires substantial additional development efforts prior to potential regulatory approval and commercial sale, including extensive clinical testing, all of which may be unsuccessful. Acquiring and developing early-stage assets would divert resources that otherwise could be used to develop and commercialize obicetrapib.

In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives. We may opportunistically pursue a strategy that would entail in-licensing additional product candidates or 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 may also become reliant on the research efforts of third parties for any such product candidates that we do not intend to conduct preclinical studies or early-stage clinical trials for. If we do not successfully develop and begin to commercialize product candidates, we will face difficulty in obtaining product revenues in future periods, which could result in significant harm to our financial position and potential for growth and adversely affect the price of the Ordinary Shares.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and management resources, we are currently primarily focused on the development of obicetrapib for cardiometabolic diseases and we may forego or delay pursuit of opportunities with other product candidates or for other indications for obicetrapib that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial product candidates or profitable market opportunities. Our spending on current and future development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Even if we obtain and maintain approval for our current and future product candidates from a regulatory authority in one or more jurisdictions, we may nevertheless be unable to obtain approval for our product candidates outside of those jurisdictions, which would limit our market opportunities and could harm our business.

Approval of a product candidate by one regulatory authority in any jurisdiction does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions. Even if one regulatory authority grants marketing approval for a product candidate, comparable regulatory authorities of other countries also must approve the manufacturing and marketing of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and more onerous than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that

we intend to charge for any product candidates, if approved, is also subject to approval. Obtaining approval for obicetrapib or any future product candidate in the EU from the European Commission following the opinion of the EMA or in other foreign jurisdictions, if we choose to submit a marketing authorization application there, would be a lengthy and expensive process. Even if a product candidate is approved, the FDA, the EMA or other foreign regulatory authorities, as the case may be, may limit the indications for which the drug may be marketed, require extensive warnings on the drug labeling or require expensive and time-consuming additional clinical trials or reporting as conditions of approval. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of obicetrapib or any future product candidate in certain countries.

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 biopharmaceutical industry is intensely competitive and subject to rapid and significant technological change. Our potential competitors include large and experienced companies that enjoy significant competitive advantages over us, such as greater financial, research and development, manufacturing, personnel and marketing resources, greater brand recognition and more experience and expertise in obtaining marketing approvals from the FDA, the EMA and other comparable regulatory authorities. These companies may develop new drugs to treat the indications that we target, or seek to have existing drugs approved for use for the treatment of the indications that we target.

If obicetrapib is approved, our main competition will come from current LDL-C lowering therapies on the market for use on top of maximally tolerated statins, such as PSCK9 inhibitor injectables from Amgen Inc., Regeneron Pharmaceuticals, Inc. and Novartis International AG. We may also face competition from oral therapeutics containing bempedoic acid from Esperion. We are aware that Merck has decided to advance its oral PSCK9 inhibitor, MK-0616, into Phase 3 development and AstraZeneca has advanced its oral PSCK9 inhibitor, AZD0780, into Phase 2 development. If approved, MK-0616 and/or AZD0780 could pose additional competition for obicetrapib.

Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in this industry. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis products that are more effective or less costly than our product candidate.

Any approved products may fail to achieve the degree of market acceptance by physicians, patients, hospitals, healthcare payors and others in the medical community necessary for commercial success.

Even if we obtain FDA, EMA or other foreign regulatory approvals for our product candidate, the commercial success of obicetrapib will depend significantly on the broad adoption and use by physicians for approved indications. The degree and rate of physician and patient adoption of obicetrapib, if approved, will depend on a number of factors, including:

- the clinical indications for which obicetrapib is approved;
- the prevalence and severity of adverse side effects;
- the pricing and extent to which the costs of obicetrapib are reimbursed by third-party payors, and patients' willingness to pay for obicetrapib;
- physicians' satisfaction with, and acceptance by the medical community and patients of, the efficacy and safety results of obicetrapib results as demonstrated in clinical trials;
- patient satisfaction with the results and administration of obicetrapib and overall treatment experience, including relative convenience, ease of use and avoidance of, or reduction in, adverse side effects;
- the extent to which physicians recommend obicetrapib to patients;
- physicians' and patients' willingness to adopt new therapies in lieu of other products or treatments;
- the timing of market introduction of obicetrapib as well as competitive products;
- the convenience of prescribing and initiating patients on obicetrapib;
- relative convenience and ease of administration of obicetrapib;
- the cost of treatment, safety and efficacy in relation to alternative treatments, including any similar generic treatments;
- the revenues and profitability that obicetrapib will offer physicians as compared to alternative therapies; and
- the effectiveness of our sales and marketing efforts.

If obicetrapib is approved for use but fails to achieve the broad degree of physician adoption and market acceptance necessary for commercial success, we will not be able to generate significant revenues, and we may not become or remain profitable.

Risks Related to Our Collaboration With or Reliance on Third Parties

We currently contract with third-party contractors for all aspects of the manufacturing of obicetrapib for clinical trials, and expect to continue to do so to support commercial scale production of obicetrapib, if approved. There are significant risks associated with contracting with third-party suppliers, including their ability to meet the increased need that may result from our potential commercialization efforts. This increases the risk that we will not have sufficient quantities of obicetrapib or be able to obtain such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We currently rely on third-party contract manufacturing organizations ("CMOs") and suppliers for all of our required raw materials, active ingredients and finished products for our clinical trials. Because there are a limited number of suppliers for the raw materials that we use to manufacture our product candidate, we may need to engage alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidate for our clinical trials, and if approved, ultimately for commercial sale. We do not have any control over the availability of raw materials. If we or our manufacturers are unable to purchase these raw materials on acceptable terms, at sufficient quality levels or in adequate quantities, if at all, the development and commercialization of our product candidate or any future product candidates would be delayed, or there would be a shortage in supply, which would impair our ability to meet our development objectives for our product candidates or generate revenues from the sale of any approved products. We currently rely on several CMOs to produce both drug substances and drug products required for our clinical trials. While we believe our existing suppliers are sufficient and that alternative sources of supply exist if needed, there can be no assurance that we will be able to quickly establish additional or replacement sources if needed, and a reduction or interruption in supply could adversely affect our ability to manufacture our product candidate in a timely or cost-effective manner. In addition, some of our CMOs and suppliers are located outside of the United States. As such, we are also subject to any global supply chain disruption that may arise as a result of geopolitical factors, public health crises, natural disasters or the potential impacts of global climate change. Global supply chain disruptions could lead to interruptions in our suppliers' production, which could impact our ability to obtain sufficient quantities of obicetrapib at an acceptable cost for our clinical trials and commercial sale, if approved.

We expect to continue to rely on our current or other subcontractors and suppliers to support our commercial requirements if obicetrapib, or any future product candidate, is approved for marketing by the FDA, the EMA or other comparable regulatory authorities. We plan to continue to rely on third parties for the raw materials, compounds and components necessary to produce our product candidates for our clinical trials.

Our continuing reliance on third-party CMOs and suppliers entails a number of risks, including reliance on the third party for regulatory compliance and quality assurance, the possible breach of the manufacturing or supply agreement by the third party, and the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. In addition, third-party CMOs and suppliers may not be able to comply with cGMP requirements, or similar regulatory requirements outside the United States. If any of these risks transpire, we may be unable to timely retain alternate subcontractors or suppliers on acceptable terms and with sufficient quality standards and production capacity, which may disrupt and delay our clinical trials or the manufacture and commercial sale of our product candidate, if approved.

Our failure or the failure of our third-party CMOs and suppliers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of obicetrapib or any other product candidates that we may develop. Any failure or refusal to supply or any interruption in supply of the components for obicetrapib or any other product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts.

The manufacture of pharmaceutical products is complex and manufacturers often encounter difficulties in production. If we or any of our third-party manufacturers encounter any difficulties, our ability to provide obicetrapib or any future product candidates for clinical trials, or to patients if approved, and the development or commercialization of obicetrapib or any future product candidates could be delayed or stopped.

The manufacture of pharmaceutical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. We and our CMOs must comply with cGMP requirements. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production and contamination controls. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

We cannot assure you that any stability or other issues relating to the manufacture of obicetrapib or any future product candidate will not occur in the future. As the manufacturing processes are scaled up, they may reveal manufacturing challenges or previously unknown impurities that could require resolution in order to proceed with our planned clinical trials and obtain regulatory approval for the commercial marketing of obicetrapib or any other products candidates we may develop. In the future, we may identify manufacturing issues or impurities that could result in delays in the clinical program and regulatory approval for obicetrapib or any future product candidate, increases in our operating

expenses or failure to obtain or maintain approval for obicetrapib or any future product candidate. Our reliance on third-party manufacturers entails risks, including the following:

- the inability to meet our product candidate specifications, including product formulation, and quality requirements consistently;
- a delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues, including those related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- a failure to comply with cGMP and similar quality standards;
- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- the reliance on a limited number of sources, and in some cases, single sources for key materials, such that if we are unable to secure a sufficient supply of these key materials, we will be unable to manufacture and sell obicetrapib in a timely fashion, in sufficient quantities or under acceptable terms;
- the lack of qualified backup suppliers for those materials that are currently or in the future purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier;
- resource constraints, including as a result of labor disputes or unstable political environments;
- carrier disruptions or increased costs that are beyond our control; and
- the failure to deliver our products under specified storage conditions and in a timely manner.

If we or our third-party manufacturers were to encounter any of these difficulties, and in particular where we rely on a single manufacturer, our ability to provide obicetrapib or any future product candidate to patients in clinical trials and products to patients, once approved, would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the initiation or completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. These events could impact our ability to obtain regulatory approval or successfully commercialize obicetrapib or any future product candidate. Some of these events could be the basis for FDA, EMA or other comparable regulatory authorities' action, including injunction, recall, seizure, or total or partial suspension of production. Any adverse developments affecting clinical or commercial manufacturing of obicetrapib or any future product candidate may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our product candidates. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could materially adversely affect our business and delay or impede the development and commercialization of obicetrapib or any future product candidate and could have a material adverse effect on our business, prospects, financial condition and results of operations.

We rely, and expect to continue to rely, on third parties and consultants to assist us in conducting our clinical trials, including our Phase 3 clinical trials for obicetrapib. If these third parties or consultants do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize obicetrapib, if approved.

We do not have the ability to independently conduct many of our clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct clinical trials on obicetrapib. Third parties play a significant role in the conduct of our clinical trials and the subsequent collection and analysis of data. These third parties are not our employees and, except for remedies available to us under our agreements, we have limited ability to control the amount or timing of resources that any such third party will devote to our clinical trials. If our CROs or any other third parties upon which we rely for administration and conduct of our clinical trials do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements, or for other reasons, or if they otherwise perform in a substandard manner, our clinical trials may be extended, delayed, suspended or terminated, and we may not be able to complete development of, obtain regulatory approval for, or successfully commercialize obicetrapib.

We and the third parties upon whom we rely are required to comply with GCP, which are regulations and guidelines enforced by regulatory authorities around the world for products in clinical development. Regulatory authorities enforce these GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or our third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and our submission of marketing applications may be delayed or the regulatory authorities may require us to perform additional clinical trials before approving our marketing

applications. We cannot assure you that, upon inspection, a regulatory authority will determine that any of our clinical trials comply or complied with applicable GCP regulations. In addition, our clinical trials must be conducted with material produced under current cGMP regulations, which are enforced by regulatory authorities. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be impacted if our CROs, clinical investigators or other third parties violate federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

In order for our clinical trials to be carried out effectively and efficiently, it is imperative that our CROs and other third parties communicate and coordinate with one another. Moreover, our CROs and other third parties may also have relationships with other commercial entities, some of which may compete with us. Our CROs and other third parties may terminate their agreements with us immediately under certain circumstances, such as upon 30 days' notice or immediately upon a material breach. If our CROs or other third parties conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical trial protocols or GCPs, or for any other reason, we may need to conduct additional clinical trials or enter into new arrangements with alternative CROs, clinical investigators or other third parties. We may be unable to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. Switching or adding CROs, clinical investigators or other third parties can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which can impact our ability to meet our desired clinical development timelines. Although we carefully manage our relationship with our CROs, clinical investigators and other third parties, there can be no assurance that we will not encounter such challenges or delays in the future or that these delays or challenges will not have a negative impact on our business, prospects, financial condition or results of operations.

We currently intend to rely on our collaboration with Menarini for the process of obtaining EMA approval for obicetrapib and the commercialization of obicetrapib, if approved, in certain European areas. Failure or delay of Menarini to fulfill all or part of its obligations to us under the Menarini License, a breakdown in collaboration between the parties or a complete or partial loss of this relationship could materially harm our business if obicetrapib is approved in the relevant jurisdictions.

While we currently plan to commercialize our own products, if approved, in the United States, we entered into the Menarini License to obtain and maintain regulatory approvals, commercialize and undertake local development, in each case with respect to obicetrapib either as a sole active ingredient product or in a fixed dose combination with ezetimibe for any use, in certain areas of Europe. Our collaboration with Menarini is critical in these areas, as we do not currently have the internal capacity to market, sell and distribute obicetrapib, if approved, in Europe. Pursuant to the Menarini License, Menarini is responsible for submitting, obtaining and maintaining EMA approvals and for communications with regulatory authorities for the commercialization and local development of obicetrapib in certain areas of Europe, if approved, and other collaborative activities. Menarini must commercialize obicetrapib pursuant to a commercialization plan agreed between the parties and is obligated to use commercially reasonable efforts to commercialize obicetrapib so as to maximize net sales, provided that Menarini has sole discretion to set the price of the products.

Either party has the right in certain circumstances to terminate the collaboration pursuant to the terms of the Menarini License, including in the case (i) of a material breach by the other party, (ii) that a relevant regulatory authority prohibits Menarini to pursue the commercialization of obicetrapib due to safety or efficacy concerns, or (iii) of insolvency of either party. If Menarini delays or fails to perform its obligations under the Menarini License, such as failure to obtain EMA approval for obicetrapib or a delay in the anticipated commercial launch of obicetrapib, disagrees with our interpretation of the terms of the collaboration or terminates the Menarini License, the commercialization of obicetrapib, if approved, could be significantly adversely affected and our prospects in Europe will be materially harmed.

We may not be able to meet our obligations under the Menarini License. Additionally, if we do not reach certain milestones as set forth in the Menarini License, we will not receive the milestone payments, which could require us to seek funding additional capital to complete clinical trials.

Menarini has also entered into collaborations with third parties addressing targets and disease indications outside the scope of our collaboration. As a result, Menarini may have competing interests with respect to their priorities and resources. We may have disagreements with Menarini with respect to the interpretation of the Menarini License, use of resources or otherwise that could cause our relationship with Menarini to deteriorate. As a result, Menarini may reduce their focus on, and resources allocated to, our commercialization, potentially delaying or terminating our ability to commercialize obicetrapib in Europe, if approved. However, as stated above, Menarini must commercialize obicetrapib pursuant to a commercialization plan agreed between the parties and is obligated to use commercially reasonable efforts to commercialize obicetrapib so as to maximize net sales. Additionally, should we decide to move forward with development of a combination of obicetrapib with a certain inhibitor in the areas of Europe covered by the Menarini License for patients suffering from diabetes, we will need to offer Menarini the opportunity to co-develop that product with us, provided that if Menarini does, we will negotiate with Menarini the economics and other terms in respect of such co-development and the subsequent commercialization of such combination product in such areas of Europe. If Menarini does not wish to co-develop such combination product, that would prevent our ability to, and our ability to license or authorize a third party to, seek regulatory approval for or promote such combination product, in the areas of Europe covered by the Menarini License.

Should the Menarini License be terminated, we will need to either build marketing, sales, distribution, managerial and other non-technical capabilities or contract with third parties to obtain these capabilities in Europe.

We have limited experience in marketing or distributing products and no internal capability to do so, and an inability to market, distribute and commercialize obicetrapib once approved would prevent us from achieving significant sales and reduce the commercial value of obicetrapib. If we are unable to establish sales, marketing and distribution capabilities for obicetrapib, if approved, or our future product candidates, or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing our product candidates, if and when they are approved.

Although we have hired a chief commercial officer, we do not have a complete sales or marketing infrastructure and, as a Company have limited experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product candidate for which we may obtain marketing approval, we will need to establish a sales and marketing organization or enter into collaboration, distribution and other marketing arrangements with one or more third parties to commercialize such product candidate. In the United States, we intend to build a commercial organization to target areas with the greatest incidence of high cardiovascular risk with residual elevation of LDL-C and recruit experienced sales, marketing and distribution professionals. The development of sales, marketing, and distribution capabilities will require substantial resources, will be time-consuming and could delay any product launch. We may decide to work with regional specialty pharmacies, distributors and/or multi-national pharmaceutical companies to leverage their commercialization capabilities to commercialize any product candidate for which we may obtain regulatory approval outside of the United States or certain areas of Europe.

If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and distribution capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization costs. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. In addition, we may not be able to hire a sales force in the United States that is sufficient in size or has adequate expertise to target the areas that we intend to target. If we are unable to establish a sales force and marketing and distribution capabilities, our operating results may be adversely affected.

Factors that may inhibit our efforts to commercialize our drugs on our own include:

•our inability to recruit, train, and retain adequate numbers of effective sales and marketing personnel;

•the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;

•the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage compared to companies with more extensive product lines;

•unforeseen costs and expenses associated with creating an independent sales and marketing organization; and

•unforeseen costs and limitations with regard to setting up a distribution network.

If we are unable to establish our own sales, marketing and distribution capabilities in the United States and other jurisdictions in which obicetrapib or any future product candidates are approved, other than in the jurisdictions covered by the Menarini License, we will be required to enter into arrangements with third parties to perform these services. As a result, our revenues and profitability, if any, are likely to be lower than if we were to sell, market and distribute any product candidates that we develop ourselves. We may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have limited control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing any product candidates.

We expect to enter into collaborations with third parties for the development or commercialization of obicetrapib or future product candidates, which involve risks that could impact our liquidity, increase our expenses and present significant distractions to our management, and we may not be able to capitalize on the market potential of obicetrapib or any future product candidate if our collaborations are not successful.

In addition to the Menarini License, we may utilize a variety of types of collaboration, distribution and other marketing arrangements with other third parties relating to the development or commercialization, once approved, of obicetrapib or future product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements.

Any future collaborations that we enter into may pose a number of risks, including the following:

•collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations;

•collaborators may not perform their obligations as expected;

•product candidates developed by collaborators may not perform sufficiently in clinical trials to be determined to be safe and effective, thereby delaying or terminating the drug approval process and reducing or eliminating milestone payments to which we would otherwise be entitled if the product candidates had successfully met their endpoints and/or received FDA or EMA approval;

•collaborators may not pursue development and commercialization of our product candidates that receive marketing approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;

•collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

•collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

•product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;

•a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;

•disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would divert management attention and resources, be time-consuming and expensive;

•collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

•collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and

•collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to the development or commercialization of product candidates in the most efficient manner, or at all. If any future collaborations that we enter into do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates. All of the risks relating to product development, regulatory approval and commercialization described in herein also apply to the activities of our collaborators.

Additionally, subject to its contractual obligations to us, if a collaborator of ours were to be involved in a business combination, it might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be harmed.

Our employees and independent contractors, including principal investigators, CROs, consultants and vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us or harm our reputation.

We are exposed to the risk that our employees, independent contractors, clinical investigators, CROs, consultants and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct, breach of contract or disclosure of unauthorized activities to us that violates regulations of the FDA, the EMA or other comparable regulatory authorities, including those laws requiring the reporting of true, complete and accurate information; manufacturing standards; federal, state and foreign healthcare fraud and abuse laws; or laws that require the reporting of financial information or data accurately.

Specifically, research, sales, marketing, education and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, education, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics and train our employees on

these topics, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, even if we are successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and reputation. Violations of such laws subject us to numerous penalties, including, but not limited to, the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

If we, or our third-party manufacturers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of its business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts, business operations and environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance.

Risks Related to Our Business and Strategy

If we fail to manage our growth effectively, our business could be disrupted.

As of December 31, 2024, we had 68 employees and 13 consultants. We expect to continue to expand our development, quality, sales, managerial, operational, finance, marketing and other resources in order to manage our operations and clinical trials, continue our development activities and commercialize obicetrapib, if approved. In addition, if we receive regulatory approval for obicetrapib, we expect to need to significantly expand our workforce to ensure a successful commercial launch of obicetrapib. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our expansion strategy requires that we:

- manage our clinical trials effectively;
- identify, recruit, retain, incentivize and integrate additional employees;
- manage our internal development efforts effectively while carrying out our contractual obligations to third parties; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

Due to our limited experience in managing a larger public company, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage expansion could delay the execution of our development and strategic objectives, or disrupt our operations; and if we are not successful in commercializing our product candidate, either on our own or through collaborations with one or more third parties, our revenues will suffer and we would incur significant additional losses.

If obicetrapib or our future product candidates receive approval for marketing, and if physicians misuse our products, we may become subject to product liability claims, and our image and reputation within the industry and marketplace could be harmed.

Physicians may also misuse our products or use improper techniques, potentially leading to adverse results, side effects or injury, which may lead to product liability claims. If our products are misused or used with improper technique, we may become subject to costly litigation. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. We currently carry product liability insurance covering our clinical trials with policy limits that we believe are customary for similarly situated companies and adequate to provide us with coverage for foreseeable risks. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Furthermore, the use of our products for conditions other than those approved by the FDA may not effectively treat such conditions, which could harm our reputation in the

marketplace among physicians and patients. If we cannot successfully manage the promotion of obicetrapib or any future product candidate, if approved, we could become subject to significant liability, which would harm our reputation and negatively impact our financial condition.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of obicetrapib or any future products we may develop.

We face an inherent risk of product liability as a result of the clinical testing of obicetrapib and will face an even greater risk if we commercialize it or any future product candidate. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidate or any future product candidates we develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants or delay or cancellation of clinical trials;
- costs to defend the related litigation, which may be only partially recoverable even in the event of successful defenses;
- a diversion of management's time and our resources;
- substantial monetary awards to clinical trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenues;
- exhaustion of any available insurance and our capital resources; and
- the inability to commercialize our product, if approved.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of any products that we may develop. We currently carry general clinical trial product liability insurance in an amount that we believe is adequate to cover the scope of our ongoing clinical programs. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If and when we obtain approval for marketing obicetrapib or any other product candidate, we intend to expand our insurance coverage to include the commercialization of obicetrapib or any other approved product that we may have; however, we may be unable to obtain this liability insurance on commercially reasonable terms.

If we fail to attract and retain senior management and key scientific personnel, we may be unable to successfully develop our product candidate, conduct our clinical trials and, if approved, commercialize our product candidate or any other products we may develop.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We believe that our future success is highly dependent upon the contributions of members of our senior management, as well as our senior scientists and other members of our management team, especially our Chief Executive Officer, Dr. Michael Davidson, our Chief Scientific Officer, Dr. John Kastelein, our Chief Operating Officer, Douglas Kling, and our Chief Financial Officer, Ian Somaiya. We are not aware of any present intention of any of these individuals to leave our company. The loss of services of any of these individuals and certain other key employees, though, could delay or prevent the successful development of our product pipeline, completion of our planned clinical trials or the commercialization of obicetrapib. Although we have agreements with our officers and employees, these agreements do not prevent them from terminating their employment or service arrangement with us as described in the agreements.

Although we have not historically experienced unique difficulties in attracting and retaining qualified employees, we could experience such problems in the future. For example, competition for qualified personnel in the pharmaceutical field is intense due to the limited number of individuals who possess the skills and experience required by our industry. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles, diverse opportunities including for career advancement and a longer history in the industry than we do. Some of these characteristics may be more appealing to high quality candidates than what we have to offer. We will need to hire additional personnel as we expand our clinical development and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from

competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output.

Misclassification or reclassification of our independent contractors or employees could increase our costs and adversely impact our business.

Our workers are classified as either employees or independent contractors, and if employees, as either exempt from overtime or non-exempt (and therefore overtime eligible). The tests governing whether a service provider is an independent contractor or an employee are typically highly fact sensitive and can vary by governing law. Laws and regulations that govern the status and misclassification of independent contractors are also subject to divergent interpretations by various authorities, which can create uncertainty and unpredictability. Regulatory authorities and private parties have recently asserted within several industries that some independent contractors should be classified as employees and that some exempt employees should be classified as nonexempt based upon the applicable facts and circumstances and their interpretations of existing rules and regulations. If we are found to have misclassified employees as independent contractors or non-exempt employees as exempt, we could face penalties and have additional exposure under tax (including federal and state tax), workers' compensation, unemployment benefits, labor, employment and tort laws, including for prior periods, as well as potential liability for employee overtime and benefits and tax withholdings. Legislative, judicial or regulatory (including tax) authorities could also introduce proposals or assert interpretations of existing rules and regulations that would change the classification of a number of independent contractors doing business with us from independent contractor to employee and a number of exempt employees to non-exempt. A reclassification in either case could result in an increase in employment-related costs such as wages, benefits and taxes. The costs associated with employee misclassification, including any related regulatory action or litigation, could therefore have an adverse effect on our results of operations and our financial position.

Under applicable employment laws, we may not be able to enforce covenants not to compete.

We generally include non-competition provisions as part of our agreements with our officers, employees and consultants. These agreements generally prohibit our officers, employees or consultants, if they cease working for us, from competing directly with us or working for our competitors for a limited period. We may be unable to enforce these provisions under the laws of the jurisdictions in which our officers, employees or consultants work and it may be difficult for us to restrict our competitors from benefitting from the expertise our former officers, employees or consultants developed while working for us.

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

We have expanded and expect to continue experiencing significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, manufacturing, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Inflation may adversely affect our operations, including increases in the prices of goods and services required for our operations.

High rates of inflation resulting from global events may adversely affect our operations in the event of increased prices of goods and services, such as energy and other operating costs, labor costs, materials costs and shipping costs, all of which may impact our direct costs. We are also experiencing increases in the cost of services provided by CMOs, CROs and other third parties with whom we do business, including significant increases in the cost of non-human primates required for studies. Such high inflation rates may result in unexpected and unbudgeted cost increases and may require changes to planned investments.

Our international operations subject us to various risks, and our failure to manage these risks could adversely affect our results of operations and we may be exposed to significant foreign exchange risk.

We face significant operational risks as a result of doing business internationally, such as:

•fluctuations in foreign currency exchange rates;

•differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;

•potentially adverse and/or unexpected tax consequences, including penalties due to the challenge by tax authorities on the basis of transfer pricing and liabilities imposed from inconsistent enforcement, as well as compliance with potentially conflicting and changing tax laws of taxing jurisdictions, the complexity and adverse consequences of such tax laws, and potentially adverse tax consequences due to changes in such tax laws;

•potential changes to the accounting standards, which may influence our financial situation and results;

•becoming subject to the different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations;

•reduced protection of, or significant difficulties in enforcing, intellectual property rights in certain countries;

•difficulties in attracting and retaining qualified personnel;

•restrictions imposed by local labor practices and laws on our business and operations, including unilateral cancellation or modification of contracts;

•rapid changes in global government, economic and political policies and conditions, political or civil unrest or instability, terrorism or epidemics and other similar outbreaks or events, and potential failure in confidence of our suppliers or customers due to such changes or events; and

•tariffs, trade protection measures, import or export licensing requirements, trade embargoes and other trade barriers.

Additionally, we incur portions of our expenses, and may in the future derive revenues, in currencies other than the U.S. dollar, in particular, the Euro. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. We currently do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the U.S. dollar. Therefore, for example, an increase in the value of the U.S. dollar against the Euro could be expected to have a negative impact on our revenue and earnings as Euro revenue and earnings, if any, would be translated into U.S. dollars at a reduced value. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations and cash flows.

Negative economic conditions, including as a result of commodity price inflation or supply chain constraints, widespread health crises, the conflict between Russia and Ukraine, the conflict in the Middle East, relations between the United States and China, and any other international conflicts or internal foreign conflicts, particularly in countries with clinical trial sites, may adversely impact our results of operations.

An unforeseen production shortage resulting from any event, including interruptions to business operations and supply chain disruption as a result of worldwide economic and political disruptions including the impacts of and the conflict in the Middle East and war between Russia and Ukraine affecting raw material and or intermediate supply or manufacturing capabilities abroad and domestically could adversely impact our business. For example, our supply chain may be disrupted, limiting our ability to manufacture our product candidates for our clinical trials and research and development operations, or our cost base may be increased. Furthermore, economic growth is expected to slow, including due to supply chain disruption, the recent surge in inflation and related actions by central banks and geopolitical conditions, with a significant risk of recession in many parts of the worlds in the near term. This may also prolong tight credit markets and potentially cause such conditions to become more severe. These issues, along with the re-pricing of credit risk and the difficulties currently experienced by financial institutions, may make it difficult to obtain financing.

Our expectations about our business, future performance and other matters are subject to significant risks, assumptions, estimates and uncertainties. As a result, our expectations regarding cash and cash burn, market size and market share, clinical trial completions, regulatory submissions and potential regulatory approvals, and our expectations regarding efficacy levels and benefits of our product candidates, may differ materially from actual results.

The estimates and assumptions included in this Annual Report and the exhibits attached, include, among others: expectations regarding our cash runway; estimates of the total addressable market for cardiometabolic disease patients with significant unmet need; assumptions regarding our ability to obtain reimbursement for our product candidate, if approved; assumptions regarding performance under existing partner agreements, including the Menarini License; and assumptions regarding our ability to obtain regulatory approval and the timing of obtaining such approvals, if ever. These estimates and assumptions are subject to various factors beyond our control, including, for example, changes in the supply of drug products required for our clinical trials, increased costs for such drugs, changes in the regulatory or competitive environment, delays in our clinical trials or in obtaining regulatory approvals, lower than expected rates of reimbursement on our product candidate, if approved, the imposition or heightening of sanctions or other economic or military measures in relation to the wars in Ukraine and Israel, and changes in our executive team. Accordingly, our future financial condition and results of operations may differ materially from our estimates.

We may undertake strategic acquisitions, in-licenses or other strategic transactions in the future and any difficulties from integrating such acquisitions could adversely affect our share price, operating results and results of operations.

We may acquire companies, businesses and products, or in-license additional product candidates, that complement or augment our existing business. Any product candidate or technologies we in-license or acquire will likely require additional development efforts prior to commercial sale, including extensive preclinical or clinical testing, or both, and approval by the FDA, the EMA and other comparable regulatory authorities, if any. All product candidates are prone to risks of failure inherent in pharmaceutical product development, including the

possibility that the product candidate, or product developed based on in-licensed technology, will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we may not be able to integrate any acquired business successfully or operate any acquired business profitably. Integrating any newly acquired business or product could be expensive and time-consuming. Integration efforts often take a significant amount of time, place a significant strain on managerial, operational and financial resources, result in loss of key personnel and could prove to be more difficult or expensive than we predict. The diversion of our management's attention and any delay or difficulties encountered in connection with any future acquisitions or in-licenses that we may consummate could result in the disruption of our on-going business or inconsistencies in standards and controls that could negatively affect our ability to maintain third-party relationships. Moreover, we may need to raise additional funds through public or private debt or equity financing, or issue additional shares, to acquire any businesses or products, which may result in dilution for shareholders or the incurrence of indebtedness.

In addition, we may not be able to manufacture economically or successfully commercialize any product candidate that we develop based on acquired or in-licensed technology that is granted regulatory approval, and such products may not gain wide acceptance or be competitive in the marketplace. Moreover, integrating any newly acquired or in-licensed product candidates could be expensive and time-consuming. If we cannot effectively manage these aspects of our business strategy, our business may be materially harmed.

As part of our efforts to acquire companies, business or product candidates or to enter into other significant transactions, we would conduct business, legal and financial due diligence with the goal of identifying and evaluating material risks involved in the transaction. Despite our efforts, we ultimately may be unsuccessful in ascertaining or evaluating all such risks and, as a result, might not realize the intended advantages of the transaction. For example, if intellectual property related to product candidates or technologies we in-license or acquire is not adequate, we may not be able to commercialize the affected products even after expending resources on their development. If we fail to realize the expected benefits from acquisitions we may consummate in the future or have consummated in the past, whether as a result of unidentified risks or liabilities, integration difficulties, regulatory setbacks, litigation with current or former employees and other events, our business, results of operations and financial condition could be adversely affected. If we acquire product candidates, we will also need to make certain assumptions about, among other things, development costs, the likelihood of receiving regulatory approval and the market for such product candidates. Our assumptions may prove to be incorrect, which could cause us to fail to realize the anticipated benefits of these potential transactions.

In addition, we will likely experience significant charges to earnings in connection with our efforts, if any, to consummate acquisitions, in-licenses or other strategic transactions. For transactions that are ultimately not consummated, these charges may include fees and expenses for investment bankers, attorneys, accountants and other advisors in connection with our efforts. Even if our efforts are successful, we may incur, as part of a transaction, substantial charges for closure costs associated with elimination of duplicate operations and facilities and acquired in-process research and development charges. In either case, the incurrence of these charges could adversely affect our results of operations for particular periods.

Cyberattacks or other failures in the telecommunications or information technology systems used by us or our third-party vendors, contractors or consultants, could result in information theft, compromise, or other unauthorized access, data corruption and significant disruption of our business operations, and could harm our reputation and subject us to liability, lawsuits and actions from governmental authorities.

Despite the implementation of security measures, including the implementation of information technology protocols to control access to our systems and information, security awareness trainings, proactive patching of known vulnerabilities, reviewing our system against specified security metrics, monitoring our third-party vendors and partners, participating in threat intelligence sharing and developing mechanisms designed to detect deviations in our systems, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from cybersecurity threats, including computer viruses, harmful code and unauthorized access, cyber-attacks (including ransomware), hacking, theft, phishing, employee error, denial-of-service attacks, social engineering schemes, sophisticated nation-state and nation-state-supported actors unauthorized accesses, natural disasters, fire, terrorism, war and telecommunication and electrical failures. We and certain of our service providers are from time to time subject to actual and attempted cyberattacks and security incidents. We do not believe that we have experienced any such material system failure or security breach to date. If a disruption event were to occur and cause interruptions in our operations or those of our third-party service providers, it could result in a material disruption to our drug development programs, and/or otherwise jeopardize the performance of our software and information technology systems, and could expose us to financial and reputational harm. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of obicetrapib could be delayed. Similarly, if an actual or attempted security incident were to occur we may be required to disclose such event and, in addition to reputational damage, we could face investigations and fines from regulators, as well as litigation. Furthermore, if we are required to disclose the occurrence of a cybersecurity incident, the price of our Ordinary Shares may be negatively impacted, whether warranted or not.

Successful and attempted attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. We may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques

used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

Global health crises may adversely affect our business and that of our suppliers, CROs or other third parties relevant to our business.

The COVID-19 pandemic impacted worldwide economic activity and future global health crises may pose the same risks, including the risk that we or our employees, contractors, suppliers, or other partners may be prevented or delayed from conducting business activities for an indefinite period of time, including due to shutdowns that may be requested or mandated by governmental authorities, which could have an adverse impact on our business, financial results and operations, as well as those of third parties on which we rely.

Risks Related to Our Intellectual Property

We may not be successful in obtaining all of the necessary intellectual property rights to allow us to develop and commercialize our product candidate, obicetrapib. If our efforts to obtain, protect or enforce our patents and other intellectual property rights related to our product candidates 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.

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 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. Although we enter into confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, CROs, CMOs, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

While we have sought and continue to actively seek patent protection for obicetrapib, our patent coverage is limited, and we can provide no assurance that any of our current or future patent applications will result in issued patents or that any issued patents will provide us with any competitive advantage.

The patent applications that we own or license may fail to result in issued patents in the United States or granted patents in foreign jurisdictions. Our ability to obtain and maintain valid and enforceable patents depends on various factors, including determination that our patent claims are patentable over prior art. We may be subject to a third-party preissuance submission of prior art to the United States Patent and Trademark Office (the "USPTO") or foreign patent offices, and such prior art may prevent issuance of claims that would provide us with a competitive advantage. We cannot be certain that we and respective patent offices have identified all relevant prior art at the time of issuance, and later identification of undiscovered prior art may provide basis for later invalidating our issued patent claims. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to the treatment of cardiometabolic disease, Alzheimer's disease, or other indications using obicetrapib or (ii) conceive and reduce to practice any of the compositions or methods claimed in our patents or patent applications, including patents or patent applications related to obicetrapib and any of our future product candidates.

Patent applications and patents granted from them are complex, lengthy and highly technical documents that are often prepared under time constraints and may not be free from errors. The existence of errors in a patent may have an adverse effect on the patent, its scope and its enforceability. Even if our pending and future patent applications issue as patents in relevant jurisdictions, they may not issue in a form that will provide us with any meaningful protection for our technology or product candidates, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Even if our pending and future patent applications issue as patents in relevant jurisdictions, changes in law or in interpretation of existing law may provide a basis for competitors to challenge the validity and/or enforceable scope of our patents.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial

value of patent rights are highly uncertain. Our pending and future owned or in-licensed patent applications may not result in patents being issued which protect our technology or product candidates, effectively prevent others from commercializing competitive technologies and products or otherwise provide any competitive advantage. In addition, the scope of claims of an issued patent can be reinterpreted after issuance, and changes in either the patent laws or interpretation of the patent laws in the United States and other jurisdictions may diminish the value of our patent rights or narrow the scope of our patent protection.

Additionally, limitations on the scope of our intellectual property rights may limit our ability to prevent third parties from designing around such rights and competing against us. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or product candidates in a non-infringing manner. Other parties may compete with us, for example, by independently developing or obtaining competing solid forms of obicetrapib, including crystalline forms and alternative salts of obicetrapib, or by independently developing or obtaining competing synthetic processes for synthesis of obicetrapib or synthetic intermediates that allow competitors to design around our patent claims but which result in the same active ingredient.

In addition, our competitors may seek to invalidate our patents. We may become involved in proceedings brought by competitors in the USPTO or applicable foreign offices challenging our patent rights, such as inter partes review, post grant review, derivation proceedings, interference proceedings, opposition proceedings, revocation proceedings or ex parte reexamination. Patent offices may take a different view on patentability during post-grant challenges than during initial examination, and courts in litigation may take a different view about validity than did the respective patent office. An adverse determination in any such submission, proceeding or litigation could result in loss of exclusivity, patent claims being narrowed, invalidated or held unenforceable, in whole or in part, or could result in limits of the scope or duration of the patent protection of our technologies or product candidates, all of which could limit our ability to stop others from using or commercializing similar or identical product candidates or technology to compete directly with us, without payment to us.

Furthermore, even if they are not challenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. To meet such challenges, which are part of the risks and uncertainties of developing and marketing product candidates, we may need to evaluate third-party intellectual property rights and, if appropriate, to seek licenses for such third-party intellectual property or to challenge such third-party intellectual property, which may be costly and may or may not be successful, which could also have an adverse effect on the commercial potential for obicetrapib and any of our other product candidates.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent prosecution process. When related patents are pursued concurrently in multiple jurisdictions, international treaties may impose additional procedural, documentary, fee payment and other provisions. Additionally, when inventions are made by joint inventors of different nationalities, or where inventive acts were performed in multiple countries, concurrent and potentially conflicting requirements imposed by the laws of multiple jurisdictions may be applicable. We may have failed to adhere to all such provisions during examination of our patent applications or following issuance.

Periodic maintenance or annuity fees and various other governmental fees on any issued patent and/or pending patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of a patent or patent application. Our outside counsel have systems in place to remind us to pay these fees, and we rely on our outside counsel and their third-party vendors to pay these fees. While an inadvertent lapse may sometimes be cured by payment of a late fee or by other means in accordance with the applicable rules, there are many situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications directed to our product candidates, our competitors might be able to enter the market earlier than should otherwise have been the case, which could harm our business, financial condition, results of operations, and prospects.

Uncertainty and instability resulting from the conflict between Russia and Ukraine could negatively impact our ability to maintain our patents in Russia.

Sanctions imposed on Russia by the United States and the European Union have made it difficult to pay required annual fees, or annuities, to maintain pending patent applications and granted patents in Russia, increasing the risk that our patents may not grant in Russia or, having granted, will lapse through nonpayment of annuities. In addition, the Russian government issued a decree in March 2022 that owners of Russian patents from countries that Russia considers to be unfriendly are no longer entitled to any compensation for compulsory licensing of their patents, increasing the risk that our competitors will be granted a compulsory license under our Russian patents, allowing them to infringe without making any payments to us.

We may receive only limited protection, or no protection, from our issued patents and patent applications and such patents could be narrowed, found invalid or unenforceable if challenged in court or before administrative bodies.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its earliest priority U.S. utility application was filed. Various extensions may be available; however the life of a patent, and the protection it affords, is limited. Without patent protection for our product candidates, we may be open to competition from generic versions of our product candidates. If we encounter delays in our clinical trials or regulatory approval of obicetrapib, the period of time during which we could market obicetrapib under patent protection could be reduced.

The patent application process, also known as patent prosecution, is expensive and time consuming, and we or any future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or any future licensors or licensees will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, etc., although we are unaware of any such defects that we believe are of material import. If we or any future licensors or licensees fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The strength of patents in the pharmaceutical field involves complex legal and scientific questions and can be uncertain. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law in ways affecting the scope or validity of issued patents. The USPTO or other foreign patent offices may change their interpretation of existing statutes or regulations with potential retroactive effects. The patent applications that we own or in-license may fail to result in issued patents in the United States or foreign countries with claims that cover our product candidates. Even if patents do successfully issue from the patent applications that we own or in-license, third parties may challenge the validity, enforceability or scope of such patents, which may result in such patents being narrowed, invalidated or held unenforceable. For example, patents granted by the European Patent Office may be challenged, also known as opposed, by any person within nine months from the publication of their grant. In addition, post grant review in the USPTO begins with a third party filing a petition on or prior to the date that is nine months after the grant of the patent or issuance of a reissue patent. Third parties can also challenge a patent in the USPTO by way of inter partes review, ex parte reexamination, derivation, or interference proceedings. Any successful challenge to our patents could deprive us of exclusive rights necessary for the successful commercialization of our product candidates. Even if such challenges to our patents are unsuccessful, the proceedings could be expensive and time consuming and may divert the efforts and attention of our technical and management personnel. Furthermore, even if they are unchallenged, our patents may not adequately protect our product candidates, provide exclusivity for our product candidates, or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our product candidates is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize our product candidates.

If we do not obtain patent term extension for our product candidates, if needed, our business may be harmed.

Under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments") which amended the FDCA, a company may file an ANDA seeking approval of a generic version of an approved innovator product. Depending upon the timing, duration and specifics of any FDA marketing approval of our product candidates and our technology, one or more of our U.S. patents that we may own in the future may be eligible for limited patent term extension under Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent may be extended and only those claims covering the approved product, a method for using it or a method for manufacturing it may be extended. The application for the extension must be submitted prior to the expiration of the patent for which extension is sought. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may not be able to protect our intellectual property rights throughout the world, or we may choose not to pursue patent rights in jurisdictions that later become important to our business, thus harming our ability to compete in those jurisdictions.

Filing, prosecuting, maintaining, and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. In countries in which we elect to pursue patent rights, the requirements for patentability may differ, particularly in developing countries. For example, China often applies a heightened requirement for patentability, with heightened requirements for experimental data in the patent application. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. For example, some foreign countries do not permit claims to therapeutic methods.

Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection in order to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement against infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally.

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

In addition, some countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

Changes in U.S. or foreign patent law, including changes in patent office interpretation of applicable rules and statutes, changes effected by judicial holdings, and changes effected by legislation, including changes that may have retroactive effect, could diminish the value of patents in general and our patents in particular, thereby impairing our ability to protect our products.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents. Obtaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity, and therefore, is costly, time-consuming and inherently uncertain. In addition, the Leahy-Smith America Invents Act (the "AIA") which was passed on September 16, 2011, resulted in significant changes to the U.S. patent system. Further, U.S. Supreme Court rulings in recent years have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained.

The significant changes to U.S. patent law under the AIA include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. For our U.S. patent applications that contain or contained at any time a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law. The USPTO has developed and continues to develop regulations and procedures to govern administration of the AIA, and many of the substantive changes to patent law associated with the AIA. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business and financial condition. It is not clear what other, if any, impact the AIA will have on the operation of our business.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued from applications filed before March 16, 2013. Because of a lower evidentiary standard necessary to invalidate a patent claim in USPTO proceedings compared to the evidentiary standard in United States federal court, a third party could potentially provide evidence in a USPTO

proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

Depending on decisions by the U.S. Congress, the federal courts, the USPTO, and foreign patent offices, the laws and regulations governing patents could change in unpredictable ways, including with potential retroactive effect, that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive and time consuming, with no certainty of success, and could delay or prevent the development and commercialization of our products and product candidates, or put our patents and other proprietary rights at risk.

Third parties may infringe or misappropriate our intellectual property, including our existing patents and patents that may issue to us in the future. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. Further, we may not be able to prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Generic drug manufacturers may develop, seek approval for, and launch generic versions of our products. If we file an infringement action against such a generic drug manufacturer, that company may challenge the scope, validity or enforceability of our patents, requiring us to engage in complex, lengthy and costly litigation or other proceedings.

For example, if we initiated legal proceedings against a third party to enforce a patent covering our product candidates, the defendant could counterclaim that the patent covering our product candidates is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent.

In addition, within and outside of the United States, there has been a substantial amount of litigation and administrative proceedings, including inter partes review, post grant review, interference or derivation proceedings, and ex parte reexamination proceedings before the USPTO or other comparable proceedings in various foreign jurisdictions, regarding patent and other intellectual property rights in the pharmaceutical industry. These proceedings bring uncertainty to the possibility of challenges to our patents in the future, including challenges by competitors who perceive our patents as blocking entry into the market for their products, and the outcome of such challenges.

Such litigation and administrative proceedings could result in revocation of our patents or amendment of our patents such that they do not cover our product candidates. They may also put our pending patent applications at risk of not issuing, or issuing with limited and potentially inadequate scope to cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. Additionally, it is also possible that prior art of which we are aware, such as may arise during preclinical studies and clinical trials, but which we do not believe affects the validity or enforceability of a claim, may, nonetheless, ultimately be found by a court of law or an administration panel to affect the validity or enforceability of a claim. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a negative impact on our business.

Enforcing our intellectual property rights through litigation would be very expensive, particularly for a company of our size, time-consuming, and inherently uncertain. Some of our competitors may be able to sustain the costs of litigation more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also divert technical and management personnel from their normal responsibilities.

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could harm our business, financial condition or results of operations.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, during the course of litigation or administrative proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price of our Ordinary Shares could be significantly harmed.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to the protection afforded by patents, we may also rely on trade secret protection or confidentiality agreements to protect proprietary know-how, technology and other proprietary information that may not be patentable or that we elect not to patent, processes for which patents may be difficult to obtain or enforce, and any other elements of our product candidates, and our product development processes (such as manufacturing and formulation technologies) that involve proprietary know-how, information or technology that is not covered by patents. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, eroding our competitive position in the market.

Trade secrets, confidential information, and know-how can be difficult to protect. We seek to protect these trade secrets and other proprietary technology, in part, by requiring all of our employees, consultants, advisors, and any other third parties that have access to our proprietary know-how, information or technology to execute confidentiality agreements upon the commencement of their relationships with us. We cannot be certain that we have or will obtain these agreements in all circumstances and we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary information. If the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secrets.

Despite our efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets. Adequate remedies may not exist in the event of unauthorized use or disclosure of our trade secrets. In addition, in some situations, these confidentiality agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, or advisors have previous employment or consulting relationships. To the extent that our employees, consultants or contractors use any intellectual property owned by third parties in their work for us, disputes may arise as to the rights in any related or resulting know-how and inventions. Any misappropriation or unauthorized disclosure of our trade secrets could have an adverse effect on our business, impact our ability to establish or maintain a competitive advantage in our market, or otherwise harm our business, operating results and financial condition.

Furthermore, trade secret protection and confidentiality agreements do not prevent competitors from independently developing substantially equivalent information and techniques and we cannot guarantee that our competitors will not independently develop substantially equivalent information and techniques. The FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all.

There is an increasing trend in the EU toward greater transparency and, while the manufacturing or quality information contained in an MAA is currently generally protected as confidential information, the EMA and national regulatory authorities may disclose much of the nonclinical and clinical information in MAAs, including the full clinical trial reports, in response to freedom of information requests after the marketing authorization has been granted. Similarly, as of January 31, 2022 under the EU Clinical Trials Regulation (EU) No 536/2014, the EU clinical trials information system allows the public to access MAA data submitted to the EMA or national regulatory authorities (excluding any commercially confidential information). There may be a risk that information that we consider to be trade secrets or other proprietary information becomes publicly available, including to our competitors, under such transparency requirements in the EU.

Third-party claims alleging intellectual property infringement may adversely affect our business, and we may be subject to lawsuits claiming that we infringe, misappropriate or otherwise violate the intellectual property rights of third parties, which could be expensive and time consuming, delay or prevent the development and commercialization of our products and product candidates, or subject future sales to royalty payments, which could damage our business.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties, for example, the intellectual property rights of competitors. Our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents owned or controlled by third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our activities related to our product candidates may give rise to claims of infringement of the patent rights of others. We cannot assure you that our product candidates will not infringe existing or future patents. We may not be aware of patents that have already issued that a third party might assert are infringed by our product candidates. It is also possible that patents of which we are aware, but which we do not believe are relevant to our product candidates, could nevertheless be found to be infringed by our product candidates. Nevertheless, we are not aware of any issued patents that we believe would prevent us or our licensee(s) from marketing our product candidates, if approved. There may also be patent applications that have been filed but not published that, when issued as patents, could be asserted against us. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that we may be subject to claims of infringement of the intellectual property rights of third parties.

Third parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. Defense of these claims, regardless of their merit, would cause us to incur substantial expenses and, and would be a substantial diversion of management time and employee resources from our business. In the event of a successful claim of infringement against us by a third party, we may have to (i) pay substantial damages, including treble damages and attorneys' fees if we are found to have willfully infringed the third party's patents; (ii) obtain one or more licenses from the third party; (iii) pay royalties to the third party; and/or (iv) redesign any infringing products. Redesigning any infringing products may be impossible or require substantial time and monetary expenditure. Further, we cannot predict whether any required license would be available at all or whether it would be available on commercially reasonable terms. In the event that we could not obtain a license, we may be unable to further develop and commercialize our product candidates, which could harm our business significantly. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into

licenses on acceptable terms. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

Defending ourselves in litigation is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could harm our business, financial condition or results of operations.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information or alleged trade secrets of third parties or competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed confidential information or trade secrets of these third parties or our employees' former employers. Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. We may also be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging our right to and use of confidential and proprietary information. If we fail in defending any such claims, in addition to paying monetary damages, we may lose our rights therein. Such an outcome could have a negative impact on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. Any litigation or the threat thereof may adversely affect our ability to hire employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, results of operations and financial condition. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of litigation proceedings could adversely affect our ability to compete in the marketplace.

We may not be able to build name recognition in our markets of interest if our trademarks and trade names are not adequately protected and our business may be adversely affected.

Our future trademark applications in the United States and other foreign jurisdictions may not be allowed or may be subsequently opposed. Once filed and registered, our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive and time-consuming, particularly for a company of our size. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations or prospects.

Disputes over intellectual property subject to the Menarini License may materially impact our ability to commercialize obicetrapib.

The licensing of intellectual property in the Menarini License is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to the Menarini License, including:

- the scope of rights granted under the Menarini License and other interpretation-related issues;
- the extent to which Menarini's technology and processes infringe our intellectual property that is not subject to the Menarini License;
- claims that our technology infringes third-party intellectual property;
- the sublicensing of patent and other rights;
- our diligence obligations and what activities satisfy those diligence obligations; and

•the ownership of inventions and know-how resulting from the joint creation or use of intellectual property.

If disputes over intellectual property we have licensed to Menarini prevent or impair our ability to maintain the Menarini License on acceptable terms, we may be unable to successfully develop and commercialize obicetrapib.

Risks Related to Government Regulation

Current and future legislation affecting the healthcare industry, including healthcare reform, may impact our business generally and may increase limitations on reimbursement, rebates and other payments, which could adversely affect third-party coverage of our products, our operations and/or how much or under what circumstances healthcare providers will prescribe or administer obicetrapib, if approved.

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell obicetrapib profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, in March 2010, President Obama signed into law the ACA, a law intended, among other things, to broaden access to health insurance, improve quality of care, and reduce or constrain the growth of healthcare spending. The ACA, among other things, imposed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, extended the rebate program to individuals enrolled in Medicaid managed care organizations, added a provision to increase the Medicaid rebate for line extensions or reformulated drugs, established annual fees on manufacturers and importers of certain branded prescription drugs and biologic agents, promoted a new Medicare Part D coverage gap discount program, expanded the entities eligible for discounts under the Public Health Service Act pharmaceutical pricing program; and imposed a number of substantial new compliance provisions related to pharmaceutical companies' interactions with healthcare practitioners. The ACA also expanded eligibility for Medicaid programs and introduced a new Patient Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research and a new Center for Medicare & Medicaid Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. In December 2017, Congress repealed the tax penalty, effective January 1, 2019, for an individual's failure to maintain ACA-mandated health insurance as part of the Tax Cuts and Jobs Act of 2017 (the "Tax Act"). President Biden issued an Executive Order that instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. Further, there have been a number of health reform initiatives by the Biden administration that have impacted the ACA. For example, on August 16, 2022, President Biden signed the IRA into law, which sets forth meaningful changes to drug product reimbursement by Medicare. Among other actions, the IRA permits HHS to engage in price-capped negotiation to set the price of certain drugs and biologics reimbursed under Medicare Part B and Part D. The IRA contains statutory exclusions to the negotiation program, including for certain orphan designated drugs for which the only approved indication (or indications) is for the orphan disease or condition. Should our product candidates be approved and covered by Medicare Part B or Part D, and fail to fall within a statutory exclusion, such as that for an orphan drug, those products could, after a period of time, be selected for negotiation and become subject to prices representing a significant discount from average prices to wholesalers and direct purchasers. The IRA also establishes a rebate obligation for drug manufacturers that increase prices of Medicare Part B and Part D covered drugs at a rate greater than the rate of inflation. The inflation rebates may require us to pay rebates if we increased the cost of a covered Medicare Part B or Part D approved product faster than the rate of inflation. In addition, the law eliminates the "donut hole" under Medicare Part D beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees' prescription costs for brand drugs below the out-of-pocket maximum and 20% once the out-of-pocket maximum has been reached. Our cost-sharing responsibility for any approved product covered by Medicare Part D could be significantly greater under the newly designed Part D benefit structure compared to the pre-IRA benefit design. Additionally, manufacturers that fail to comply with certain provisions of the IRA may be subject to penalties, including civil monetary penalties. The IRA is anticipated to have significant effects on the pharmaceutical industry and may reduce the prices we can charge and reimbursement we can receive for our products, among other effects.

In addition, other federal health reform measures have been proposed and adopted in the United States since the ACA was enacted. For example, as a result of the Budget Control Act of 2011, providers are subject to Medicare payment reductions of 2% per fiscal year, which went into effect on April 1, 2013. This 2% reduction was temporarily suspended during the COVID-19 pandemic, but has since been reinstated and, unless Congress and/or the Executive Branch take additional action, will begin to increase gradually starting in April 2030, reaching 4% in April 2031, until sequestration ends in October 2031. Further, the American Taxpayer Relief Act of 2012 reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments from providers from three to five

years. The Medicare Access and CHIP Reauthorization Act of 2015 also introduced a quality payment program under which certain individual Medicare providers will be subject to certain incentives or penalties based on new program quality standards. In November 2019, CMS issued a final rule finalizing the changes to the Medicare Quality Payment Program. On May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 30, 2020, HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The IRA delayed the implementation of the rule to January 1, 2032. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers; the implementation of these provisions has also been delayed by the IRA until January 1, 2032.

On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate price cap, currently set at 100% of a drug's average manufacturer price for single source and innovator multiple source products, beginning on January 1, 2024. Further, in July 2021, the Biden administration released an executive order that included multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug price reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions by HHS. No legislative or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of the budget reconciliation process. Additionally, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subjects drug manufacturers to civil monetary penalties and a potential excise tax for offering a price that is not equal to or less than the negotiated "maximum fair price" under the law, and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Specifically, 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 and 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 Part 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 9 years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. Nonetheless, since CMS may establish a maximum price for these products in price negotiations, we would be fully at risk of government action if our products are the subject of Medicare price negotiations. Moreover, given the risk that could be the case, these provisions of the IRA may also further 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 if prices are set after such products have been on the market for nine years.

These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry. If healthcare policies or reforms intended to curb healthcare costs are adopted, or if we experience negative publicity with respect to the pricing of obicetrapib, if approved, or any future product or the pricing of pharmaceutical drugs generally, the prices that we charge for any approved products may be limited, our commercial opportunity may be limited and/or our revenues from sales of our products may be negatively impacted.

If we obtain regulatory approval and commence commercialization of obicetrapib or any of our future product candidates, these laws may result in additional reductions in healthcare funding, which could have an adverse effect on our customers and accordingly, our financial operations. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of obicetrapib or our future product candidates may be.

Although we cannot predict the full effect on our business of the implementation of existing legislation or the enactment of additional legislation pursuant to healthcare and other legislative reform, we believe that legislation or regulations that would reduce reimbursement for, or restrict coverage of, obicetrapib, if approved, or any of our future products could adversely affect how much or under what circumstances healthcare providers will prescribe or administer our products. This could adversely affect our business by reducing our ability to generate

revenues, raise capital, obtain licenses and market our products. In addition, we believe the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of pharmaceutical products, which may adversely impact product sales.

In April 2023, the EU Commission released proposals to amend the current EU pharmaceutical regulatory framework. The potential reforms include shortening the periods of regulatory and/or marketing protections available for innovative products. Depending on the final wording of these reforms (if adopted), a reduction in the periods of regulatory and/or marketing protections available for obicetrapib or any of our future product candidates may adversely affect the commercial viability of such products in the EU. These changes could adversely affect our business by reducing our protection against generic competitors entering the EU market. Depending on the progress of the EU Parliament and Council, changes to EU pharmaceutical legislation are not expected to come into force until 2025 or 2026 and additional transitional periods mean that the changes will most likely not take effect until 2027 or 2028.

Our relationships with healthcare professionals, independent contractors, clinical investigators, CROs, consultants and vendors in connection with our current and future business activities may be subject to federal, state and foreign healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face penalties.

We may currently be or may become subject to various federal, state and foreign healthcare laws, including those intended to prevent healthcare fraud and abuse.

The federal Anti-Kickback Statute prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid Remuneration has been broadly defined to include anything of value, including, but not limited to, cash, improper discounts, and free or reduced price items and services.

Much like the federal Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of EU member states. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain EU member states must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU member states. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Federal false claims laws, including the FCA and civil monetary penalties law impose penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent or making a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government. The FCA has been used to, among other things, prosecute persons and entities submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. The FCA includes a whistleblower provision that allows individuals to bring actions on behalf of the federal government and share a portion of the recovery of successful claims.

Many states have similar fraud and abuse statutes and regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. State and federal authorities have aggressively targeted medical technology companies for, among other things, alleged violations of these anti-fraud statutes, based on improper research or consulting contracts with doctors, certain marketing arrangements that rely on volume-based pricing, off-label marketing schemes, and other improper promotional practices.

HIPAA among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services.

Our operations will also be subject to the federal transparency requirements under the ACA, which require certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to annually report to the CMS an agency within HHS information related to payments and other transfers of value provided to physicians, teaching hospitals, certain ownership and investment interests held by physicians and their immediate family members and certain non-physician providers (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified-nurse midwives). On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation ("MFN") executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation, challenging the MFN model on August 10, 2021, CMS published a proposed rule that seeks to rescind the MFN model interim rule. In addition, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate price cap, currently set at 100% of a drug's average manufacturer price for single source and innovator multiple source

products, beginning on January 1, 2024. Further, in July 2021, the Biden administration released an executive order that included multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug price reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions by HHS. No legislative or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of the budget reconciliation process. Additionally, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law, and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges.

We may also be subject to federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products, and similar laws in other jurisdictions.

We are subject to stringent privacy laws, information security policies and contractual obligations governing the use, processing, and cross-border transfer of personal information and our data privacy and security practices.

We receive, generate and store sensitive information, including employee and patient data, and are subject to a variety of federal, state, local and foreign laws and regulations that apply to the collection, use, retention, protection, disclosure, transfer and other processing of data in the jurisdictions in which we operate, including comprehensive regulatory systems in the United States and the EU. Legal requirements relating to data processing continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement, sanctions and increased costs of compliance. An actual or perceived failure to comply with laws and regulations governing personal information could result in government investigations and enforcement actions against us, fines, claims for damages by affected third parties, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

EU data protection laws including the GDPR impose strict requirements relating to the processing of personal data, including special protections for "special categories of personal data" which includes, without limitation, health and genetic information of data subjects residing in the EU. The GDPR also generally prohibits the transfer of personal information from the EU to the United States and most other foreign jurisdictions unless the parties to the transfer have implemented specific safeguards to protect the transferred personal information. There is uncertainty regarding how to ensure that transfers of personal information from the EU to the United States comply with the GDPR. As such, any transfers by us, or our vendors, of personal information from the EU may not comply with EU data protection laws; may increase our exposure to the GDPR's heightened sanctions for violations of its cross-border data transfer restrictions; and may reduce demand for our services from companies subject to EU data protection laws. Loss of our ability to transfer personal information from the EU may also require us to increase our data processing capabilities in those relevant jurisdictions at significant expense.

Similar privacy and data security requirements are either in place or have been proposed in the United States. There are numerous data protection laws that may be applicable to our activities, and a range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission and state Attorneys General are aggressive in reviewing privacy and data security protections for consumers. New laws also are being considered or have been implemented at both the state and federal levels.

Further, regulations promulgated pursuant to HIPAA impose privacy, security and breach notification obligations on health plans, healthcare clearinghouses and certain healthcare providers, known as covered entities, as well as their business associates that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities, and their covered subcontractors. HIPAA establishes privacy and security standards that limit the use and disclosure of protected health information ("PHI") and requires the implementation of administrative, physical and technological safeguards to protect the privacy of PHI and ensure the confidentiality, integrity and availability of electronic PHI. Most healthcare providers, including research institutions from which we obtain patient health information, are subject to HIPAA. We do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly subject to its requirements. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information.

Complying with the GDPR and other U.S. and foreign data protection laws and regulations may cause us to incur substantial operational costs or require us to change our business practices in a manner adverse to our business.

Moreover, complying with these various laws could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Despite our efforts to bring our practices into compliance with these laws and regulations, we may not be successful in our efforts to achieve compliance either due to internal or external factors such as resource allocation limitations or a lack of vendor cooperation. Failure to comply with U.S. and international data

protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), other administrative actions or litigation. For example, the GDPR sets out substantial fines for breaches of the data protection rules, increased powers for regulators, enhanced rights for individuals, and new rules on judicial remedies and collective redress. Any inability to adequately address privacy concerns, even if unfounded, or comply with applicable privacy or data protection laws, regulations and policies, could result in additional cost and liability to us, damage our reputation, inhibit sales and adversely affect our business, results of operations and financial condition.

Our marketing efforts may be subject to a variety of regulations.

We may choose to conduct marketing activities, directly and indirectly, via text (SMS) messages, email, and/or through other online and offline marketing channels. Numerous foreign, federal, and state regulations may govern such marketing activities, including the Telemarketing Sales Rule, the Telephone Consumer Protection Act ("TCPA"), state and federal Do-Not-Call regulations and other state telemarketing laws, federal and state privacy laws, the CAN-SPAM Act, and the Federal Trade Commission Act and its accompanying regulations and guidelines, among others. These laws not only allow action to be brought by regulatory agencies, but some of these laws, like the TCPA, allow private individuals to bring litigation against companies for breach of these laws. If we conduct marketing activities regulated by these laws, then we may depend on third-party partners to comply with these laws. Any lawsuit brought by private individuals, or action by a regulatory agency, for an actual or alleged violation of applicable law or regulation by us or our third-party partners may have an adverse effect on our business, results of operations, and financial condition.

We could be adversely affected by violations of the FCPA and other worldwide anti-bribery laws, export and import controls, sanctions, embargoes, and anti-money laundering laws and regulations.

Various of our activities may be subject to anti-bribery, export control and import laws and regulations, including the U.S. Foreign Corrupt Practices Act ("FCPA"), the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the jurisdictions in which we conduct activities. Anti-corruption laws have been interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. These laws are complex and far-reaching in nature, and, as a result, we cannot assure you that our internal control policies and procedures will protect us from reckless or negligent acts committed by our intermediaries, or that we would not be required in the future to alter one or more of our practices to mitigate risk under these laws or to be responsive to any changes in these laws or the interpretation thereof. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. Furthermore, because we engage, and expect to continue to engage, third parties in connection with our clinical trials and other development and commercialization activities, we can be held liable for the corrupt or other illegal activities of our personnel, agents or collaborators, even if we do not explicitly authorize or have prior knowledge of such activities. Other companies in the biopharmaceutical field have faced criminal or civil penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with individuals in the public or private sector.

Any violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees, and could result in a material adverse effect on our business, prospects, financial condition, or results of operations or our reputation. We could also suffer severe penalties, including substantial criminal and civil penalties, imprisonment, disgorgement, reputational harm and other remedial measures.

It may be difficult for us 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 our 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. Such authorities and other third-party payors are increasingly challenging the prices charged for healthcare products, examining the cost effectiveness of drugs in addition to their safety and efficacy, and limiting or attempting to limit both coverage and the level of reimbursement for prescription drugs. We cannot be sure that coverage will be available for obicetrapib or our other product candidates, if approved, or, if coverage is available, the level of reimbursement.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within HHS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors often follow CMS. It is difficult to predict what CMS as well as other payors will decide with respect to reimbursement.

Reimbursement may impact the demand for, and/or the price of, any product for which we obtain marketing approval. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their

prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA, the EMA or other comparable regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution.

Reimbursement by a third-party payor may depend upon a number of factors including the third-party payor's determination that use of a product is:

•a covered benefit under its health plan;

•safe, effective and medically necessary;

•appropriate for the specific patient;

•cost-effective; and

•neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor. Further, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. We may not be able to provide data sufficient to gain acceptance with respect to coverage and/or sufficient reimbursement levels.

We cannot be sure that coverage or adequate reimbursement will be available for obicetrapib or any of our future product candidates, if approved. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our future products, which would in turn negatively affect revenues from any future sales. If reimbursement is not available, or is available only to limited levels that are not commercially attractive to us or our collaborators, we may not be able to commercialize obicetrapib or our other product candidates, or achieve profitability, even if approved.

Marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in foreign jurisdictions.

We intend to seek approval to market our current and future product candidates in the United States, the EU and selected other foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some countries, particularly certain EU member states, the pricing of drugs is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures.

In the EU, the requirements governing drug pricing and reimbursement vary widely between EU member states. Some EU member states provide that products may be marketed only after a reimbursement price has been agreed. Some EU member states may require the completion of additional studies that compare the cost effectiveness of a particular product candidate to currently available therapies (so called health technology assessments) in order to obtain reimbursement or pricing approval. Moreover, at the national level, EU member states may restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU member states may approve a specific price for a product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU member states allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many EU member states have increased the amount of discounts required on pharmaceuticals and these efforts could continue as EU member states attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the EU. The downward pressure on health care costs in general, particularly prescription products, has become significant. As a result, increasingly high barriers are being erected to the entry of new products in the marketplace. Political, economic and regulatory developments in the EU may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel trade (arbitrage between low-priced and high-priced member states) can further reduce prices. Acceptance of any medicinal product for reimbursement may come with cost, use and often volume restrictions, which again can vary by country. In addition, results based rules of reimbursement may apply. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if

approved in those countries. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales and the potential profitability of any of our product candidates in those countries would be negatively affected. In April 2023, the EU Commission released proposals to amend the current EU pharmaceutical regulatory framework. The potential reforms, if adopted, and depending on their final form, may cause additional pressure on pricing issues across the EU. For example, certain additional periods of regulatory exclusivity will only be available to medicinal products that are released and continuously supplied in a sufficient quantity and in the presentations necessary to cover the needs of the patients in every member state within two years of authorization (for products authorized through the centralized procedure). The potential commercial value of such a benefit may disproportionately affect pricing negotiations in member states that may otherwise be lower priority markets. However, the EU Parliament and Council are yet to agree on the final wording of any proposed legislation. Depending on the progress of the EU Parliament and Council, any changes to EU pharmaceutical legislation are not expected to come into force until 2025 or 2026 at the earliest. Additional transitional periods mean that the changes will most likely not take effect until 2027 or 2028.

We are subject to changing law and regulations regarding regulatory matters, corporate governance and public disclosure that have increased both our costs and the risk of noncompliance.

We are subject to rules and regulations by various governing bodies, including, for example, the SEC, who are charged with the protection of investors and the oversight of companies whose securities are publicly traded, and to new and evolving regulatory measures under applicable law. Our efforts to comply with new and changing laws and regulations have resulted in increased selling, general and administrative expenses. Moreover, because these laws, regulations and standards are subject to varying interpretations, their application in practice may evolve over time as new guidance becomes available. This evolution may result in continuing uncertainty regarding compliance matters and additional costs necessitated by ongoing revisions to our disclosure and governance practices. If we fail to address and comply with these regulations and any subsequent changes, we may be subject to penalty and our business may be harmed. For example, as of December 31, 2024, we no longer qualify as an emerging growth company and as a result will be subject to more stringent reporting and compliance requirements applicable to larger companies.

Legislative or regulatory healthcare reforms in the United States or abroad may make it more difficult and costly for us to obtain regulatory clearance or approval of obicetrapib or any of our future product candidates now or in the future and to produce, market and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress or by governments in foreign jurisdictions that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture, and marketing of regulated products or the reimbursement thereof. In addition, FDA, EMA or other comparable regulatory authority regulations and guidance are often revised or reinterpreted by the FDA, the EMA or other comparable regulatory authorities in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of obicetrapib or any of our other product candidates now or in the future. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- changes to manufacturing methods;
- change in protocol design;
- additional treatment arm (control);
- recall, replacement, or discontinuance of one or more of our products; and
- additional recordkeeping.

Each of these would likely entail substantial time and cost and could harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for obicetrapib or any future products would harm our business, financial condition and results of operations.

Risks Related to Our Financial Position

Our ability to use our tax losses to offset future taxable income may be subject to certain limitations.

Our ability to utilize tax losses and tax loss carryforwards is conditioned upon it attaining profitability and generating taxable income. We have incurred significant tax losses since inception and it is anticipated that we will continue to incur significant losses. As of December 31, 2024, we disclosed unused tax losses of $570.6 million. Additionally, our ability to utilize tax losses and tax loss carryforwards to offset future taxable income may be subject to certain limitations. In this respect, as of January 1, 2022, tax losses can be carried back one year and carried forward indefinitely in the Netherlands. However, both the carry back and carry forward tax loss relief will be limited to 50% of the taxable profit to the extent it exceeds EUR 1 million, calculated per financial year. As a result of transitional law, tax losses incurred in the financial

years that started on or after January 1, 2013 (our oldest tax loss year as of December 31, 2023) and that are still available for carry forward as of January 1, 2025 also fall under the new scheme that entered into effect on January 1, 2022 and will therefore be indefinite. In addition, pursuant to Article 20a of the Dutch Corporate Income Tax, tax loss carryforwards can no longer be offset against future taxable profits if the ultimate ownership in a Dutch taxpayer has changed by an amount equal to or greater than 30%, unless certain counter evidence rules are met. In this respect, we believe and have taken the position that the tax losses of NewAmsterdam Pharma B.V. available for carry forward have not been forfeited as a result of the change of ownership back in 2020, when NewAmsterdam Pharma acquired all shares in the capital of NewAmsterdam Pharma B.V. (formerly Dezima Pharma B.V.), and that the tax losses of NewAmsterdam Pharma and NewAmsterdam Pharma B.V. have not been forfeited as a result of the Business Combination. On May 25, 2022, we filed a ruling request with the Dutch Tax Authorities to confirm that the change of ownership back in 2020 (described above) did not result in the loss of the tax losses of NewAmsterdam Pharma B.V. available for carry forward at that time. However, as of the date hereof, the Dutch Tax Authorities had not yet decided on our request. We currently expect, but can in no way guarantee or enforce, that the Dutch Tax Authority will grant our request.

We are a holding company with no operations and rely on operating subsidiaries to provide it with funds necessary to meet our financial obligations.

We are a holding company that does not conduct any business operations of its own. As a result, we are largely dependent upon cash dividends and distributions and other transfers, including for dividends or payments in respect of any indebtedness we may incur, from our subsidiaries to meet its obligations.

Any agreements governing indebtedness that we or our subsidiaries enter into may impose restrictions on our subsidiaries' ability to pay dividends or other distributions to us. Each of our subsidiaries is a distinct legal entity, and under certain circumstances legal and contractual restrictions may limit our ability to obtain cash from such subsidiaries. The deterioration of the earnings from, or other available assets of, our subsidiaries for any reason could also limit or impair their ability to pay dividends or other distributions to us.

United States tax authorities could treat us as a PFIC, which could result in adverse U.S. federal income tax consequences to U.S. Holders.

Based on current estimates of the composition of the income and assets of the Company and its subsidiaries for the taxable year ended December 31, 2024, we do not expect to be treated as a passive foreign investment company ("PFIC") for U.S. federal income tax purposes for the 2024 taxable year. We have not yet determined whether we expect to be a PFIC for any future taxable years. Under the U.S. Internal Revenue Code of 1986, as amended (the "Code"), a non-U.S. corporation is classified as a PFIC for U.S. federal income tax purposes in the applicable tax year if, after the application of certain "look-through" rules with respect to subsidiaries, (i) at least 75% of its gross income in a taxable year, including its pro rata share of the gross income of any corporation in which it is considered to own at least 25% of the shares by value, is "passive income" or (ii) at least 50% of the value of its assets in a taxable year, ordinarily determined on the basis of quarterly averages, is attributable to assets that produce or are held for the production of "passive income." The determination of whether the Company or any of its non-U.S. subsidiaries is a PFIC is made annually and thus subject to change, and it generally cannot be made until the end of the taxable year. Additionally, any taxpayer who held a share of a class of our stock during a year in which we were treated as a PFIC will be required to continue to treat such class of stock as stock in a PFIC, unless the taxpayer made a timely "qualified electing fund" or "mark-to-market" election, as described below, or if the taxpayer makes a deemed sale or deemed dividend election.

Passive income generally includes dividends, interest, royalties, rents (other than certain rents and royalties derived in the active conduct of a trade or business), annuities and gains from assets that produce passive income. Cash is a passive asset for PFIC purposes, even if held as working capital. For this purpose, a non-U.S. corporation is generally treated as owning a proportionate share of the assets and earning a proportionate share of the income of any other corporation in which it owns, directly or indirectly, at least 25% (by value) of the stock. Accordingly, the Company will be treated as owning the cash and other cash-equivalent items of FLAC.

A U.S. Holder (as defined below) generally will be subject to additional U.S. federal income taxes and interest charges on the gain from a sale of Ordinary Shares and on receipt of an "excess distribution" with respect to Ordinary Shares or any of its non-U.S. subsidiaries. Under proposed regulations, a U.S. Holder may also be subject to additional U.S. federal income taxes and interest charges on the gain from the sale of the Public Warrants (as defined below), and the warrants to purchase Ordinary Shares initially issued as part of a unit issued in a private placement concurrently with the closing of FLAC's initial public offering (the "Private Placement Warrants"). A U.S. Holder of stock of a PFIC generally may mitigate these adverse U.S. federal income tax consequences, however, by making a "qualified electing fund" election or a "mark-to-market" election. If we determine that we and/or any of our subsidiaries is a PFIC for any taxable year, we intend to provide a U.S. Holder such information as the United States Internal Revenue Service (the "IRS") may require, including a PFIC Annual Information Statement, in order to enable the U.S. Holder to make and maintain a "qualified electing fund" election with respect to the Company and/or such non-U.S. subsidiaries, but there can be no assurance that we will be able to timely provide such required information.

U.S. Holders generally will not be able to make a qualified electing fund election solely with respect to the Warrants.

A "U.S. Holder" is a holder who, for U.S. federal income tax purposes, is a beneficial owner of securities and is:

•an individual who is a citizen or individual resident of the United States;

•a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state therein or the District of Columbia;

•an estate the income of which is subject to U.S. federal income taxation regardless of its source; or

•a trust if (1) a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or (2) the trust has a valid election to be treated as a U.S. person under applicable U.S. Treasury Regulations.

Risks Related to Ownership of Our Securities

Sales of a substantial number of our securities in the public market by certain of our securityholders pursuant to a registration statement we filed and/or by our existing securityholders could cause the price of our Ordinary Shares and Warrants to fall.

We filed a registration statement on Form F-1 (Registration No. 333-268888) registering up to 60,724,388 Ordinary Shares (the "Resale Shares") for resale by certain of our securityholders. The Resale Shares represent a substantial percentage of our outstanding Ordinary Shares and Warrants, and the sales of such securities, or the perception that those sales might occur, could depress the market price of our Ordinary Shares and Warrants and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our Ordinary Shares and Warrants but the sale of a large number of securities could result in a significant decline in the public trading price of our securities.

We are a Dutch public limited liability company. The rights of our shareholders may be different from the rights of shareholders in companies governed by the laws of other jurisdictions and may not protect investors in a similar fashion afforded by incorporation in such other jurisdiction.

In connection with the Business Combination, the Company was converted into a public limited liability company (*naamloze vennootschap*) under Dutch law. Our corporate affairs are governed by our articles of association (the "Articles of Association"), the rules of the Board of Directors, our other internal rules and policies and by Dutch law. There can be no assurance that Dutch law will not change in the future or that it will serve to protect shareholders in a similar fashion afforded under corporate law principles in other jurisdictions, which could adversely affect the rights of our shareholders.

In the performance of their duties, our directors are required by Dutch law to consider the interests of the Company, its shareholders, its employees and other stakeholders, in all cases with due regard to the principles of reasonableness and fairness. It is possible that some of these stakeholders will have interests that are different from, or in addition to, your interests as a shareholder.

For more information on relevant provisions of Dutch corporation law and of the Articles of Association, see the description of our capital stock included in Exhibit 4.4 and our Articles of Association filed as Exhibit 3.1 to this Annual Report.

The market price and trading volume of the Ordinary Shares and Public Warrants may be volatile and could decline significantly.

The Nasdaq Global Market on which we have listed the Ordinary Shares and warrants to purchase Ordinary Shares (the "Public Warrants") under the symbols "NAMS" and "NAMSW," respectively, have from time to time experienced significant price and volume fluctuations. There may not be an active trading market for Ordinary Shares, which may make it difficult to sell such shares. Even if an active, liquid and orderly trading market develops and is sustained for the Ordinary Shares and Public Warrants, the market price of the Ordinary Shares and Public Warrants may be volatile and could decline significantly. In addition, the trading volume in the Ordinary Shares and Public Warrants may fluctuate and cause significant price variations to occur. If the market price of the Ordinary Shares and Public Warrants decline significantly, you may be unable to resell your shares or warrants at or above the price at which you acquired the Ordinary Shares and/or Public Warrants. We cannot assure you that the market price of the Ordinary Shares and Public Warrants will not fluctuate widely or decline significantly in the future in response to a number of factors, including, among others, the following:

•the realization of any of the risk factors presented in herein;

•adverse results, or perceived adverse results, or delays in our clinical trials,

•additions and departures of key personnel;

•failure to comply with the requirements of Nasdaq;

•failure to comply with the Sarbanes-Oxley Act of 2002 ("Sarbanes-Oxley") or other laws or regulations;

•future issuances, sales, resales or repurchases or anticipated issuances, sales, resales or repurchases, of Ordinary Shares, including due to the expiration of contractual lock-up agreements;

•publication of research reports about the Company;

•failure to meet expectations of investors or securities analysts;

•the performance and market valuations of other similar companies;

•new laws, regulations, subsidies, or credits or new interpretations of existing laws applicable to the Company;

•commencement of, or involvement in, litigation involving the Company;

•broad disruptions in the financial markets, including sudden disruptions in the credit markets;

•speculation in the press or investment community;

•actual, potential or perceived control, accounting or reporting problems;

•actual or anticipated differences in the Company's estimates, or in the estimates of analysts, for the Company's revenues, results of operations, liquidity or financial condition;

•changes in accounting principles, policies and guidelines;

•general economic conditions in the United States and abroad, including high interest rates, rising inflation, the liquidity concerns at certain financial institutions, and the potential for local and/or global economic recession; and

•other events or factors, including those resulting from infectious diseases, health epidemics and pandemics, natural disasters, war, acts of terrorism or responses to these events.

In the past, securities class-action litigation has often been instituted against companies following periods of volatility in the market price of their shares. This type of litigation could result in substantial costs and divert our management's attention and resources, which could have a material adverse effect on us.

There can be no assurance that the Ordinary Shares or the Public Warrants will be able to comply with the continued listing standards of Nasdaq.

Our Ordinary Shares are traded on Nasdaq under the symbol "NAMS" and our Public Warrants are traded on Nasdaq under the symbol "NAMSW." If we fail to satisfy the continued listing requirements of Nasdaq such as the minimum closing bid price requirement, Nasdaq may take steps to delist our securities. Such a delisting would likely have a negative effect on the price of the securities and would impair your ability to sell or purchase the securities when you wish to do so. In such a delisting, we and our shareholders could face significant material adverse consequences including:

•a limited availability of market quotations for our securities;

•reduced liquidity for our securities;

•a determination that our stock is a "penny stock" which will require brokers trading in our stock to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for shares of our stock;

•a limited amount of analyst coverage; and

•a decreased ability to issue additional securities or obtain additional financing in the future.

In the event of a delisting, we can provide no assurance that any action taken by it to restore compliance with listing requirements would allow its securities to become listed again, stabilize the market price or improve the liquidity of its securities, prevent its securities from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements. Additionally, if our securities are not listed on, or become delisted from, Nasdaq for any reason, and are quoted on the OTC Bulletin Board, an inter-dealer automated quotation system for equity securities that is not a national securities exchange, the liquidity and price of our securities may be more limited than if they were quoted or listed on Nasdaq or another national securities exchange. You may be unable to sell your securities unless a market can be established or sustained.

If securities or industry analysts do not publish or cease publishing research or reports about the Company, our business, or the market in which we operate, or if they change their recommendations regarding the Ordinary Shares adversely, then the price and trading volume of the Ordinary Shares could decline.

The trading market for our Ordinary Shares and Public Warrants will be influenced by the research and reports that industry or financial analysts publish about our business. We do not control these analysts, or the content and opinions included in their reports. If any of the analysts who cover us issues an inaccurate or unfavorable opinion regarding the Company, the price of the Ordinary Shares would likely decline. If one or more of these analysts cease coverage of the Company or fail to publish reports on it regularly, our visibility in the financial markets could decrease, which in turn could cause its share price or trading volume to decline.

We do not intend to pay dividends for the foreseeable future. Accordingly, you may not receive any return on investment unless you sell your Ordinary Shares for a price greater than the price you paid for them.

We have never declared or paid any cash dividends on its shares. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on the Ordinary Shares in the foreseeable future. Consequently, you may be unable to realize a gain on your investment except by selling such shares after price appreciation, which may never occur.

The Board of Directors may only pay dividends and other distributions from the Company's reserves to the extent the Company's shareholders' equity (*eigen vermogen*) exceeds the sum of the paid-in and called-up share capital plus the reserves it must maintain under Dutch law or the Articles of Association and (if it concerns a distribution of profits) after adoption of its statutory annual accounts by its general meeting of its shareholders (the "General Meeting") from which it appears that such dividend distribution is allowed. Subject to those restrictions, any future determination to pay dividends or other distributions from the Company's reserves will be at the discretion of the Board of Directors and will depend upon a number of factors, including its results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors the Board of Directors deems relevant.

Under the Articles of Association, the Board of Directors may decide that all or part of the profits shown in the Company's adopted statutory annual accounts will be added to its reserves. After reservation of any such profits, any remaining profits will be at the disposal of the General Meeting at the proposal of the Board of Directors for distribution on Ordinary Shares, subject to applicable restrictions of Dutch law. The Board of Directors is permitted, subject to certain requirements and applicable restrictions of Dutch law, to declare interim dividends without the approval of the General Meeting. Dividends and other distributions will be made payable no later than a date determined by the Company. Claims to dividends and other distributions not made within five years from the date that such dividends or distributions became payable will lapse and any such amounts will be considered to have been forfeited to us (*verjaring*).

Our management team has limited experience managing a public company.

Most members of our management team have limited experience managing a publicly traded company, interacting with public company investors, and complying with the increasingly complex laws, rules and regulations that govern public companies. As a public company, we are subject to significant obligations relating to reporting, procedures and internal controls, in both the United States and the Netherlands, and our management team may not successfully or efficiently manage such obligations. These obligations and scrutiny will require significant attention from our management and could divert their attention away from the day-to-day management of our business, which could adversely affect our business, financial condition and results of operations. In connection with the Business Combination, the Company's legal form was converted from a private company with limited liability to a public limited liability company in the Netherlands. Additional burdens were imposed on our management team as a result of such conversion.

Investors may have difficulty enforcing civil liabilities against the Company or the members of the Board of Directors.

We are organized and existing under the laws of the Netherlands. As such, under Dutch private international law, the rights and obligations of our shareholders vis-à-vis the Company originating from Dutch corporate law and our Articles of Association, as well as the civil liability of our officers (*functionarissen*) including our directors and executive officers are governed in certain respects by the laws of the Netherlands.

We are not a resident of the United States and our officers may also not all be residents of the United States. As a result, depending on the subject matter of the action brought against us and/or our officers, United States courts may not have jurisdiction. If a Dutch court has jurisdiction with respect to such action, that court will apply Dutch procedural law and Dutch private international law to determine the law applicable to that action. Depending on the subject matter of the relevant action, a competent Dutch court may apply another law than the laws of the United States.

Also, service of process against non-residents of the United States can in principle (absent, for example, a valid choice of domicile) not be effected in the United States.

On the date of this Annual Report, (i) there is no treaty in force between the United States and the Netherlands for the reciprocal recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters and (ii) both the Hague Convention on Choice of Court Agreements (2005) and the Hague Judgments Convention (2019) have entered into force for the Netherlands, but have not entered into force for the United States. Consequently, a judgment rendered by a court in the United States will not automatically be recognized and enforced by the competent Dutch courts. However, if a person has obtained a judgment rendered by a court in the United States that is enforceable under the laws of the United States and files a claim with the competent Dutch court, the Dutch court will in principle give binding effect to that United States judgment if (i) the jurisdiction of the United States court was based on a ground of jurisdiction that is generally acceptable according to international standards, (ii) the judgment by the United States court was rendered in legal proceedings that comply with the Dutch standards of proper administration of justice including sufficient safeguards (*behoorlijke rechtspleging*), (iii) binding effect of such United States judgment is not contrary to Dutch public order (*openbare orde*) and (iv) the judgment by the United States court is not incompatible with a decision rendered between the same parties by a Dutch court, or with a previous decision rendered between the same parties by a foreign court in a dispute that concerns the same subject and is based on the same cause, provided that the previous decision qualifies for recognition in the Netherlands. Even if such a United States judgment is given binding effect, a claim based thereon may, however, still be rejected if the United States judgment is not or no longer formally enforceable. Moreover, if the United States judgment is not

final (for instance when appeal is possible or pending) a competent Dutch court may postpone recognition until the United States judgment will have become final and refuse recognition, under the understanding that recognition can be asked again once the United States judgment will have become final, or impose as a condition for recognition that security is posted.

A competent Dutch court may deny the recognition and enforcement of punitive damages or other awards. Moreover, a competent Dutch court may reduce the amount of damages granted by a United States court and recognize damages only to the extent that they are necessary to compensate actual losses or damages. Finally, there may be specific other instances, including pursuant to anti-boycott rules and regulations, where Dutch law prohibits the recognition and enforcement of a United States judgment. Thus, United States investors may not be able, or may experience difficulty, to enforce a judgment obtained in a United States court against us or our officers.

The Articles of Association provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended (the "Securities Act") and the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which could limit the ability of our securityholders to choose a favorable judicial forum for disputes with we or our directors, officers or employees.

The Articles of Association provide that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum for any complaint asserting a cause of action arising under the Securities Act or the Exchange Act, to the fullest extent permitted by applicable law, shall be the U.S. federal district courts. This choice of forum provision may increase a securityholder's cost and limit the securityholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us or our directors, officers and other employees. Our shareholders will not be deemed to have waived compliance with the U.S. federal securities laws and the rules and regulations thereunder as a result of the exclusive forum provision. Any person or entity purchasing or otherwise acquiring any of the Ordinary Shares or other securities, whether by transfer, sale, operation of law or otherwise, will be deemed to have notice of and have irrevocably agreed and consented to this provision. There is uncertainty as to whether a court would enforce such provision. The Securities Act provides that state courts and federal courts will have concurrent jurisdiction over claims under the Securities Act, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. It is possible that a court could find this type of provisions to be inapplicable or unenforceable, and if a court were to find this provision in the Articles of Association to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could have adverse effect on our business and financial performance.

Our principal shareholders and management own a significant percentage of our Ordinary Shares and have representation on the Board of Directors and will be able to control matters subject to shareholder approval.

As of December 31, 2024, our executive officers, directors and holders of 5% or more of our capital stock beneficially owned approximately 49.7% of our outstanding Ordinary Shares (assuming that none of the 1,886,137 Earnout Shares have been issued). Certain of our directors are also affiliated with certain of our greater than 5% shareholders. As a result of the foregoing, these shareholders may be able to significantly influence the outcome of matters submitted for director action, subject to obligation of the Board of Directors to act in the interest of all of our stakeholders, and for shareholder action, including the designation and appointment of the Board of Directors and approval of significant corporate transactions, including business combinations, consolidations and mergers. The influence of these shareholders over our management could have the effect of delaying or preventing a change in control or otherwise discouraging a potential acquirer from attempting to obtain control of the Company, which could cause the market price of our Ordinary Shares to decline or prevent our shareholders from realizing a premium over the market price for their Ordinary Shares. Investors in our Ordinary Shares should consider that the interests of these shareholders may differ from their interests in material respects.

If we fail to maintain an effective system of internal control over financial reporting or disclosure controls, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which is likely to negatively affect our business and the market price of the Ordinary Shares and Public Warrants.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting and disclosure controls. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). As a result of becoming a public company, we were required, pursuant to Sarbanes-Oxley, to maintain internal control over financial reporting. Effective internal control over financial reporting and disclosure controls are necessary for us to provide reliable financial reports, prevent fraud and comply with our Exchange Act reporting obligations, and efforts to ensure that there are effective internal control over financial reporting and disclosure controls are costly, time-consuming, and need to be re-evaluated frequently. Any failure to implement required new or improved controls, or difficulties encountered in our implementation could cause us to fail to meet our reporting obligations. In addition, any testing conducted by us, or any testing conducted by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which is likely to negatively affect our business and the market price of the Ordinary Shares.

We are required to disclose changes made in our internal controls and procedures on an annual basis and our management will be required to assess the effectiveness of these controls annually beginning with our fiscal year ending December 31, 2023. However, for as long as we are an "emerging growth company" under the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"), our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404(b) of Sarbanes-Oxley. Because the market value of our Ordinary Shares held by non-affiliates exceeded $700 million as of June 30, 2024, we ceased to qualify as an emerging growth company as of December 31, 2024 after which our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

Inferior internal controls could also cause investors to lose confidence in our reported financial information, which is likely to negatively affect our business and the market price of the Ordinary Shares.

We have identified material weaknesses in our internal control over financial reporting in the past. If we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business and the price of our securities.

In connection with the preparation of our financial statements at and for the years ended December 31, 2023, 2022 and 2021, our management identified material weaknesses in the design of our internal control over financial reporting across the principles for each component of the COSO framework at the entity level (i.e. control environment, risk assessment, monitoring, information & communication and control activities) and accordingly, across its business and IT processes. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be detected or prevented on a timely basis. Specifically, the material weaknesses that were identified, individually or in the aggregate, included the following:

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

As a result of these material weaknesses in our internal control over financial reporting, our management concluded that as of December 31, 2023, our disclosure controls and procedures were not effective. As described in more detail in Item 9A of Part II of this Annual Report, our management, under the oversight of the Audit Committee, took steps to remediate the identified material weaknesses, which steps consisted primarily of engaging additional personnel and establishing the internal control framework. As of the date of this Annual Report, the identified material weaknesses have been remediated.

There can be no assurance that the measures we have taken to date, and actions we may take in the future, will be sufficient to prevent or avoid potential future material weaknesses. If we identify future material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports, the market price of our Ordinary Shares may decline as a result, and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities. Failure to remediate any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

We may redeem your unexpired warrants prior to their exercise at a time that is disadvantageous to you, thereby making your warrants worthless.

We have the ability to redeem all outstanding Warrants at any time after they become exercisable and prior to their expiration, at a price of $0.01 per warrant, if, among other things, the closing price of the Ordinary Shares equals or exceeds $18.00 per share (as adjusted for share sub-divisions, share capitalizations, reorganizations, recapitalizations and the like) 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"). If and when the Warrants become redeemable by us, we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws. Redemption of the outstanding Warrants as described above could force you to (i) exercise your Warrants and pay the exercise price therefor at a time when it may be disadvantageous for you to do so, (ii) sell your Warrants at the then-current market price when you might otherwise wish to hold your Warrants or (iii) accept the nominal redemption price which, at the time the outstanding Warrants are called for redemption, is likely to be substantially less than the market value of your Warrants. None of the Private Placement Warrants will be redeemable by us so long as they are held by Frazier Lifesciences Sponsor LLC or its permitted transferees.

In addition, we have the ability to redeem the outstanding Warrants at any time after they become exercisable and prior to their expiration, at a price of $0.10 per warrant if, among other things, the Reference Value equals or exceeds $10.00 per share (as adjusted for share sub-divisions, share dividends, rights issuances, reorganizations, recapitalizations and the like) and the former holders of the Private Placement Warrants have also been called for redemption, subject to certain limitations as set forth in the Warrant Assignment, Assumption and Amendment Agreement, dated November 22, 2022, between us, Continental Stock Transfer & Trust Company and FLAC (the "Warrant Assumption Agreement"). In such a case, the holders will be able to exercise their Warrants prior to redemption for a number of Ordinary Shares determined based on the redemption date and the fair market value of the Ordinary Shares. The value received upon exercise of the Warrants (1) may be less than the value the holders would have received if they had exercised their Warrants at a later time where the underlying share price is higher and (2) may not compensate the holders for the value of the Warrants, including because the number of Ordinary Shares received is capped at 0.361 shares of the Ordinary Shares per warrant (subject to adjustment) irrespective of the remaining life of the warrants.

Warrants and options to purchase Ordinary Shares will become exercisable for Ordinary Shares, which would increase the number of shares eligible for future resale in the public market and result in dilution to shareholders.

As of December 31, 2024, Warrants to purchase an aggregate of 2,632,581 Ordinary Shares and Pre-Funded Warrants to purchase an aggregate of 7,514,231 Ordinary Shares were outstanding and are exercisable in accordance with the terms of the Warrant Assumption Agreement. The exercise price of the Warrants is $11.50 per share. To the extent such warrants are exercised, additional Ordinary Shares will be issued, which will result in dilution to the holders of Ordinary Shares and increase the number of Ordinary Shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market or the fact that such Warrants and Pre-Funded Warrants may be exercised could adversely affect the market price of Ordinary Shares. To the extent that the Warrants are "out-of-the-money" we do not expect that all of the Warrant holders will exercise their Warrants. As such, there is no guarantee that the Warrants will ever be exercised. As of December 31, 2024, there were 19,029,056 Ordinary Shares issuable upon the exercise of options granted under the LTIP, Rollover Plan, Supplementary LTIP and Inducement Plan at a weighted average exercise price of $10.04. If the options are exercised, there may be additional Ordinary Shares offered which may further adversely affect the market price of our Ordinary Shares.

There is no guarantee that the Warrants will be in the money, and they may expire worthless.

Pursuant to the terms of the Warrant Assumption Agreement, the Warrants will expire on November 23, 2027, at 5:00 p.m., Eastern Standard Time. The exercise price of our Warrants is $11.50 per Ordinary Share, subject to adjustment. The exercise price of the Warrants has at times exceeded the market price of the Ordinary Shares. To the extent the price of our Ordinary Shares remains below $11.50, we believe that Warrant holders will be unlikely to cash exercise their warrants, resulting in little to no cash proceeds to us. There is no guarantee the exercise price of our Warrants will ever remain below the price of our Ordinary Shares and, as such, our Warrants may expire worthless.

The terms of the Public Warrants may be amended in a manner adverse to a holder if holders of at least 65% of the then outstanding Public Warrants approve of such amendment.

The Warrant Assumption Agreement provides that (i) the terms of the Warrants may be amended without the consent of any holder for the purpose of (a) curing any ambiguity or correct any mistake, including to conform the provisions of the Warrant Assumption Agreement to the description of the terms of such warrants and the Warrant Assumption Agreement set forth in this Annual Report, or defective provision, (b) amending the definition of "Ordinary Cash Dividend" as contemplated by and in accordance with the Warrant Assumption Agreement or (c) adding or changing any provisions with respect to matters or questions arising under the Warrant Assumption Agreement as the parties to the Warrant Assumption Agreement may deem necessary or desirable and that the parties deem to not adversely affect the rights of the registered holders of such warrants under the Warrant Assumption Agreement and (ii) all other modifications or amendments require the vote or written consent of at least 65% of the then outstanding Public Warrants; provided that any amendment that solely affects the terms of the Private Placement Warrants or any provision of the Warrant Assumption Agreement solely with respect to the Private Placement Warrants will require at least 50% of the then outstanding Private Placement Warrants.

Accordingly, we may amend the terms of the Public Warrants in a manner adverse to a holder if holders of at least 65% of the then outstanding Public Warrants approve of such amendment. Although the ability to amend the terms of the Public Warrants with the consent of at least 65% of the then outstanding Public Warrants is unlimited, examples of such amendments could be amendments to, among other things, increase the exercise price of the warrants, shorten the exercise period or decrease the number of Ordinary Shares purchasable upon exercise of a warrant.

The Warrant Assumption Agreement designates the courts of the State of New York or the United States District Court for the Southern District of New York as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by holders of Warrants, which could limit the ability of Warrant holders to obtain a favorable judicial forum for disputes with us.

The Warrant Assumption Agreement provides that, subject to applicable law, (i) any action, proceeding or claim against us arising out of or relating in any way to the Warrant Assumption Agreement, including under the Securities Act, will be brought and enforced in the courts of the State of New York or the United States District Court for the Southern District of New York, and (ii) that we will irrevocably submit to such jurisdiction, which jurisdiction will be the exclusive forum for any such action, proceeding or claim.

Notwithstanding the foregoing, these provisions of the Warrant Assumption Agreement do not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal district courts of the United States of America are the sole and exclusive forum. Any person or entity purchasing or otherwise acquiring any interest in any of the Warrants will be deemed to have notice of and to have consented to the forum provisions in the Warrant Assumption Agreement. If any action, the subject matter of which is within the scope of the forum provisions of the Warrant Assumption Agreement, is filed in a court other than a court of the State of New York or the United States District Court for the Southern District of New York (a "foreign action") in the name of any holder of Warrants, such holder will be deemed to have consented to: (x) the personal jurisdiction of the state and federal courts located in the State of New York in connection with any action brought in any such court to enforce the forum provisions (an "enforcement action"), and (y) having service of process made upon such warrant holder in any such enforcement action by service upon such warrant holder's counsel in the foreign action as agent for such Warrant holder.

This choice-of-forum provision may limit a Warrant holder's ability to bring a claim in a judicial forum that it finds favorable for disputes, which may discourage such lawsuits. Alternatively, if a court were to find this provision of the Warrant Assumption Agreement inapplicable or unenforceable with respect to one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could materially and adversely affect its business, financial condition and results of operations and result in a diversion of the time and resources of management and the Board of Directors.

Our shareholders may not have any preemptive rights in respect of future issuances of Ordinary Shares, and, as a result, may experience substantial dilution upon future issuances of Ordinary Shares or grants of rights to subscribe for such shares.

In the event of an issuance of Ordinary Shares or a grant of rights to subscribe for Ordinary Shares, subject to certain exceptions, each shareholder will have a pro rata pre-emption right in proportion to the aggregate nominal value of such holder's Ordinary Shares. These pre-emption rights may be restricted or excluded by a resolution of the General Meeting or by another corporate body designated by the General Meeting. The Board of Directors is authorized for a period of five years from November 21, 2022 to issue Ordinary Shares or grant rights to subscribe for Ordinary Shares up to the Company's authorized share capital from time to time and to limit or exclude pre-emption rights in connection therewith. This issuance of Ordinary Shares or grant of rights to subscribe for Ordinary Shares without pre-emptive rights for existing shareholders could cause existing shareholders to experience substantial dilution of their interest in the Company.

We are not obligated to, and do not, comply with all best practice provisions of the Dutch Corporate Governance Code.

We are subject to the Dutch Corporate Governance Code (the "DCGC"). The DCGC contains principles and best practice provisions on corporate governance that regulate relations between the board and the general meeting and matters in respect of financial reporting, auditors, disclosure, compliance and enforcement standards. The DCGC is based on a "comply or explain" principle. Accordingly, companies must disclose in their statutory annual reports whether they comply with the provisions of the DCGC. If a company subject to the DCGC does not comply with those provisions, that company would be required to give the reasons for such non-compliance. We do not comply with all best practice provisions of the DCGC. This may affect your rights as a shareholder and you may not have the same level of protection as a shareholder in a Dutch company that fully complies with the DCGC.

Provisions of our Articles of Association or Dutch corporate law might deter acquisition bids for the Company that might be considered favorable and prevent, delay or frustrate any attempt to replace or dismiss directors.

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 of Directors. These include:

- a provision that the Company's directors can only be appointed on the basis of a binding nomination prepared by the Board of Directors 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 of Directors 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 of Directors 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 of Directors.

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 of Directors 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 of Directors. If exercising such rights may result in a change in our strategy (for example, through the dismissal of one or more directors), the Board of Directors 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 of Directors 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 of Directors 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 of Directors 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 of Directors 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 of Directors. During a cooling-off period, the Board of Directors 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 of Directors 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 of Directors, 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 of Directors 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).

As of January 1, 2024, we are no longer a foreign private issuer, and we are required to comply with the provisions of the Exchange Act and the rules of Nasdaq applicable to U.S. domestic issuers, which will continue to require us to incur significant expenses and expend time and resources. significant additional costs and expenses and subject us to increased regulatory requirements.

We determined on June 30, 2023 that we no longer satisfied the requirements for retaining our foreign private issuer status which means that as of January 1, 2024 we are required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. The Exchange Act reporting and other requirements applicable to U.S. domestic issuers, including periodic reporting requirements and the U.S. federal proxy rules, are more detailed and extensive than the requirements for foreign private issuers. We were required to make changes in our corporate governance practices in accordance with various SEC and Nasdaq rules. We were also required to begin preparing our financial statements in accordance with U.S. GAAP which resulted in financial statements that are different than our historical financial statements and which may make it difficult for investors to compare our financial performance over time. Our officers, directors and principal shareholders became subject to the reporting and short-swing profit disclosure and recovery provisions of Section 16 of the Exchange Act. As a U.S. listed public company that is not a foreign private issuer, we expect to incur significant additional legal, accounting and other expenses that we did not incur as a foreign private issuer. We also expect that complying with the rules and regulations applicable to U.S. domestic issuers may make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our management team and Board of Directors. Complying with the Exchange Act rules applicable to a domestic company will require additional time from management and could divert their attention away from the day-to-day management of our business, which could adversely affect our business, financial condition and results of operations. may also distract our management team and impact our operations.

Dutch and European insolvency laws are substantially different from U.S. insolvency laws and may offer our shareholders less protection than they would have under U.S. insolvency laws.

As a Dutch public limited liability company, we are subject to Dutch insolvency laws in the event any insolvency proceedings are initiated against us including, among other things, Regulation (EU) 2015/848 of the European Parliament and of the Council of May 20, 2015 on insolvency proceedings. Should courts in another EU member state determine that our center of main interests ("COMI") is situated in that member state, the courts in that member state will in principle have jurisdiction over the insolvency proceedings initiated against us and the insolvency laws of that member state will in principle apply to us, in accordance with and subject to such EU regulations. Insolvency laws in the Netherlands or the relevant other EU member state, if any, may offer our shareholders less protection than they would have under U.S. insolvency laws and make it more difficult for our shareholders to recover the amount they could expect to recover in a liquidation or restructuring under U.S. insolvency laws.

We no longer qualify as an "emerging growth company" as of December 31, 2024 and, as a result, we are no longer able to avail ourselves of certain reduced disclosure requirements applicable to emerging growth companies.

As of December 31, 2024, we no longer qualify as an emerging growth company within the meaning of Section 2(a) of the Securities Act, as modified by the JOBS Act. As such, we are subject to certain disclosure and compliance requirements that apply to other public companies but did not previously apply to us due to our status as an emerging growth company. These requirements include, but are not limited to:

- the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act of 2002;
- compliance with any requirement that may be adopted by the Public Company Accounting Oversight Board ("PCAOB") regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, including critical audit matters;
- the requirement that we provide full and more detailed disclosures regarding executive compensation; and
- the requirement that we hold a non-binding advisory vote on executive compensation and obtain stockholder approval of any golden parachute payments not previously approved.

The loss of EGC status and compliance has increased and may continue to increase our legal and financial compliance costs, and may cause management and other personnel to divert attention from operational and other business matters to devote substantial time to public company reporting requirements.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

As part of our ongoing company-wide risk assessment, our management team has identified several key categories of cybersecurity risk to which we are exposed, including, (i) data security risks, (ii) malware and phishing attacks, (iii) insider and third-party risks, (iv) infrastructure and network risks and (v) regulatory and compliance risks. We identified the above risks based on an analysis of our business and a technical analysis by our information and communications technology ("ICT") consultants of our most critical business activities and associated vulnerabilities. We review our systems against specified security metrics to ensure they are satisfactory, monitor our third-party vendors and partners, participate in threat intelligence sharing, have developed mechanisms designed to detect deviations in our systems, have implemented information technology protocols to control access to our systems and information, provide security awareness trainings, and proactively patch known vulnerabilities. We are working with third-party consultants to build our cybersecurity incident detection processes, including taking the steps described above, and are also working with our vendors and partners to ensure that we are made aware of any cybersecurity incident they experience that may impact our business promptly. In addition, we maintain policies and processes to assess and manage risks relating to third-party service providers, including based on the nature of the engagement with the third party and based on the information and information systems to which the third party will have access. We maintain policies to conduct due diligence before onboarding new service providers and maintain ongoing evaluations to ensure compliance with our security standards. Our management team, along with ICT consultants and other advisors, will conduct a risk assessment on at least an annual basis in order to ensure we are appropriately managing known cybersecurity risks and discovering any potentially new risks. To date, we have not identified any material impact on our business strategy, results of operations or financial condition resulting from the cybersecurity risks described above. However, there can be no assurances that the steps we take will be sufficient to avoid a cybersecurity incident and, if an incident were to occur, our business may be materially impacted as a result of any costs associated with remediating a cybersecurity incident or resolving litigation or regulatory enforcement actions as a result such incident, or potential delays to our clinical trials or release of data as a result of an incident impacting our internal systems or those of the CROs on whom we rely to conduct our clinical trials and gather data from such trials. Furthermore, the realization of any of the risks described above could seriously harm our reputation making it more difficult to recruit patients and CROs, conduct clinical trials, obtain regulatory approvals for our current or future product candidates or generate partnering opportunities.

Our Audit Committee oversees the application of our ICT systems and all risks relating to cybersecurity. Cybersecurity is a standing agenda item at each of the Audit Committee's regularly scheduled meetings and the committee may engage any external advisor as needed to

advise on cybersecurity matters. The Audit Committee periodically reports on such matters to the Board of Directors as part of our overall risk management and oversight framework. We have also established a management-level disclosure committee (the "Disclosure Committee"). The Disclosure Committee, which consists of employees representing our legal, finance, IT, regulatory and clinical departments, is responsible for overseeing the preparation of our public disclosure materials and assessing the materiality of events within the Company. The Disclosure Committee is also responsible for conducting our cybersecurity risk assessment and ensures constituencies from across the Company are represented in such assessment. The Disclosure Committee monitors cybersecurity incidents and risk on an ongoing basis and may engage outside consultants as needed to assess and respond to cybersecurity incidents. The Disclosure Committee reports to the Audit Committee on a variety of matters, including cybersecurity risks. In addition, our Senior Vice President of Information Technology has significant experience managing IT departments, including with regard to cybersecurity risk management and compliance. We have also engaged a third party to provide technical information technology experience to the Disclosure Committee, Audit Committee and Board of Directors.

Item 2. Properties

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

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

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

Item 3. 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.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholders Matters and Issuer Purchases of Equity Securities

Market for Ordinary Shares

Our Ordinary Shares trade on the Nasdaq Global Market under the symbol "NAMS."

Record Holders

As of February 18, 2025, we had approximately 26 holders of record of our Ordinary Shares, one of which was Cede & Co., a nominee for Depository Trust Company ("DTC"). Ordinary Shares that are held by financial institutions as nominees for beneficial owners or in "street name" are deposited into participant accounts at DTC and are considered to be held of record by Cede & Co. as one shareholder.

Dividends

We have never declared or paid a cash dividend on our Ordinary Shares and do not anticipate paying any cash dividends in the foreseeable future.

Unregistered Sales of Securities

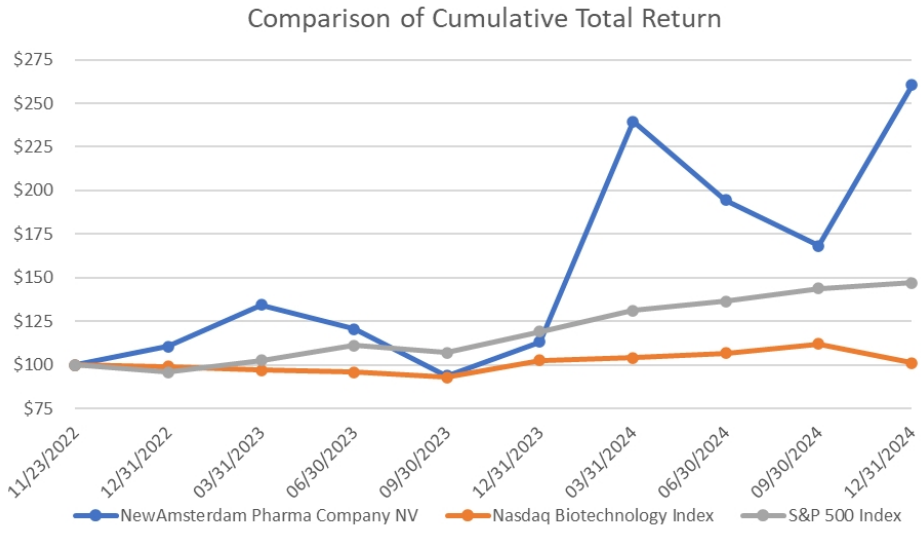
We did not sell or issue any equity securities during the fiscal year ended December 31, 2024 that were not registered under the Securities Act.

Stock Price Performance Graph

The following performance graph shall not be deemed "soliciting material" or to be "filed" with the SEC for purposes of the Exchange Act or otherwise subject to the liabilities under that section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act or the Exchange Act.

The following graph shows a comparison from November 23, 2022, the date on which our Ordinary Shares first began trading on Nasdaq, through December 31, 2024 of the cumulative total return for our Ordinary Shares, the Nasdaq Biotechnology Index, and the Standard & Poor's 500 Stock Index (the "S&P 500") each of which assumes an initial investment of $100 and reinvestment of all dividends. Such returns are based on historical results and are not intended to suggest future performance.

The comparisons shown in the graph below are based upon historical data. We caution that the stock price performance shown in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our Ordinary Shares.



Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical financial information, the following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those contained in or implied by any forward-looking statements. Factors that could cause or contribute to these differences include those under "Risk Factors" included in Part I, Item 1A and under "Special Note Regarding Forward-Looking Statements" or in other parts of this Annual Report on Form 10-K.

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 LDL-C lowering therapy. In multiple Phase 3 trials, we have investigated obicetrapib, an oral, low-dose, once-daily, highly selective 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 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 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 TESAEs. We have observed obicetrapib to be well tolerated in an aggregate of over 3,500 patients with 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 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 positive trend in the exploratory MACE endpoint and we are performing a Phase 3 CVOT PREVAIL trial 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, ApoB, and 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 LDL particles and more specifically small LDL particles, which are believed to be more atherogenic particles.

CVD is a leading cause of death worldwide. 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 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 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.

As of December 31, 2024, we had cash and cash equivalents of $771.7 million as compared to $340.5 million as of December 31, 2023. The increase in cash is primarily driven by the proceeds of the February 2024 Offering (as defined below), the December 2024 Offering (as defined below), Warrant exercises, exercises of options and the achievement of a clinical development milestone, partially offset by cash outflows related to research and development costs as we continue development of obicetrapib and increased spending on selling, general and administrative expenses to support our growing organization.. As of December 31, 2024, we no longer qualify as an "emerging growth company," and, as a result, we are no longer able to avail ourselves of certain reduced reporting requirements applicable to emerging growth companies, and we expect to incur increased expenses as a result.

Recent Developments

December 2024 Follow-On Offering

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 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.

Positive Topline Data from Pivotal Phase 3 BROADWAY Clinical Trial

On December 10, 2024, we announced positive topline data from our Phase 3 BROADWAY clinical trial. The primary endpoint was the least-squares mean of the percent change in LDL-C from baseline to day 84 for obicetrapib 10 mg compared to placebo, using imputation for missing data. The primary endpoint was achieved with statistical significance with an LDL-C reduction of 33% ($p<0.0001$). As part of the safety analysis, the trial adjudicated MACE as an exploratory endpoint, including death, non-fatal myocardial infarction, non-fatal stroke and coronary revascularization. In addition, a 21% reduction in MACE favoring obicetrapib was observed. The observed changes in other biomarkers, including HDL-C, non-HDL-C, Lp(a), ApoB, and Apolipoprotein A1 (ApoA1) were consistent with data reported in our prior clinical trials. As part of the safety analysis, key AEs of special interests were monitored. Among these AEs, glycemic control and renal function were monitored and each of the events favored obicetrapib. Overall, obicetrapib was also observed to be well-tolerated, with safety results, including blood pressure, comparable to placebo.

Positive Topline Data from Pivotal Phase 3 TANDEM Clinical Trial

On November 20, 2024, we announced positive topline data from our Phase 3 TANDEM clinical trial. The 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, including the obicetrapib-ezetimibe fixed dose combination achieving an LS mean reduction of 48.6% ($p < 0.0001$) compared to placebo at day 84. In the trial, the fixed-dose combination of obicetrapib and ezetimibe was observed to be well tolerated, with safety results comparable to placebo.

Positive Topline Data from Pivotal Phase 3 BROOKLYN Clinical Trial

On November 18, 2024, we announced additional positive data from our Phase 3 BROOKLYN clinical trial. The trial met its primary endpoint of percent change from baseline in LDL-C of obicetrapib 10 mg compared to placebo after 84 days. The trial also met several of its prespecified secondary endpoints with statistical significance and observed results consistent with our prior clinical trials. Key secondary endpoints 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. The p-value for the LS mean for all secondary endpoints compared to placebo was <0.0001 following 84 days of treatment with obicetrapib. Obicetrapib was also observed to be well tolerated, with safety results in the treatment arm comparable to placebo and no observed increase in blood pressure.

Components of our Results of Operations

Revenue

To date, we have not generated any revenue from the sale of pharmaceutical products. Our revenue has been solely derived from our license agreement with Menarini. 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"). Pursuant to the Menarini License, we received a non-refundable, non-creditable upfront amount of $120.9 million (€115.0 million) from Menarini on July 7, 2022, of which $98.6 million (€93.5 million) was

attributed to the license performance obligation and recognized as revenue upon the execution of the Menarini License on June 23, 2022. The remaining $22.3 million (€21.5 million) was attributed to the R&D performance obligation and initially recognized as deferred revenue.

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. Due to the scientific uncertainties around the commercialization of the Licensed Products based on the success of clinical trials, which is out of our control, the fixed €27.5 million was considered constrained at contract execution and is not initially recognized within the transaction price until it becomes highly probable of no significant revenue reversal. At the end of each reporting period, we assess the probability of significant reversals for any amounts that become likely to be realized prior to recognizing the constrained amounts associated with these payments within the transaction price.

Under the Menarini License, we are also entitled to receive certain cost sharing payments, sales-based royalties and payments based upon the achievement of defined development, regulatory and commercial milestones linked to the enhanced value of the license performance obligation. These milestones are contingent payments and represent variable considerations 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. Our ability to receive and generate revenue from these payments is dependent upon a number of factors, including our ability to successfully complete the development of and obtain regulatory approval for obicetrapib within the Menarini Territory. The uncertainty of achieving these milestones significantly impacts our ability to generate revenue. At the end of each reporting period, we assess the probability of significant reversals for any amounts that become likely to be realized prior to recognizing the variable consideration associated with these payments within the transaction price.

We do not expect to generate any revenue from product sales for the foreseeable future. Any revenue generated from potential future collaborations may vary due to the many uncertainties in the development of obicetrapib and other factors.

Research and Development Expenses

Research and development expenses are recognized as an expense when incurred and are typically made up of costs from our clinical and preclinical activities, drug development and manufacturing costs, and costs for CROs 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 provided by vendors of their actual costs incurred. At each balance sheet date, we estimate the level of services provided by vendors and the associated expenditure incurred for the services performed.

All such costs are for the purpose of advancing our product candidate to successfully complete clinical development, attain regulatory approval and, if approved, commercialize our product candidate. Much of our current focus in our ongoing trials is on patient recruitment and retention and data cleaning. Research and development expenses consist of the following:

- clinical expenses primarily incurred by CROs assisting with our sponsored clinical trials and including clinical investigator costs, patient enrollments and costs of clinical sites;
- manufacturing expenses arising from API and drug product development as performed by our CMOs, which are used in our clinical trials and research and development activities;
- costs associated with obtaining potential regulatory approval of our product candidate, including preparation and submission of filings, ongoing monitoring and compliance with comments and recommendations provided by regulatory authorities, and regulatory-related advisory fees;
- contracted personnel and employment costs attributed to research and development efforts, which includes management fees, salaries, share-based compensation expenses, bonus plans and payments to contractors who work for us for a fixed number of hours per week or per month;
- preclinical and nonclinical research and development expenses of the product candidate; and
- other clinical costs such as clinical trial insurance and other consultancy fees.

We expect our research and development expenses to be significant as we advance obicetrapib through clinical trials and pursue regulatory approval. The process of conducting the necessary clinical trials to obtain regulatory approval is costly and time-consuming. Clinical trials generally become larger and more costly to conduct as they advance into later stages and, in the future, we will be required to make estimates for expense accruals related to clinical trial expenses. At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of obicetrapib. See the section entitled "*Risk Factors—Risks Related to Our Product Development, Regulatory Approval and Commercialization*" for more information regarding the risks associated with clinical development.

Selling, General and Administrative Expenses

We recognize selling, general and administrative expenses on the accrual basis when incurred. These expenses mainly relate to consultant fees, employee costs, legal costs, marketing and communication, intellectual property costs due to increased efforts to drug patent development and protection globally, and general overhead costs.

Due to the general growth of the organization associated with administering ongoing and planned clinical trials and our focus on commercial preparedness, we expect that our selling, general and administrative expenses may increase. We will incur increased accounting, audit, legal, regulatory, compliance, director and officer insurance costs as well as investor and public relations expenses associated with being a public company. Additionally, if and when a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and expenses as a result of our preparation for commercial operations.

Interest Income

Interest income is recognized using the effective interest rate method. Finance income for the year ended December 31, 2024 is related to interest earned on cash, cash equivalents and marketable securities.

Net Foreign Exchange Gain/Loss

Our exchange gain/loss relates mainly to cash balances denominated in foreign currencies, but also to transactions denominated in foreign currencies. Our foreign currency exposure is mainly related to the Euro. As of December 31, 2024, our net exposure to foreign currency risk was $108.6 million compared to $114.3 million as of December 31, 2023, mainly related to the Euro.

Income Tax

We have a history of losses and therefore have de minimis amounts of corporate tax. We expect to continue incurring losses as we continue to invest in our clinical and preclinical development programs. Consequently, any deferred tax assets are fully offset by a valuation allowance on our balance sheet.

Results of Operations

Comparison of the Years Ended December 31, 2024 and December 31, 2023

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

(In thousands of USD)	For the year ended December 31, 2024	2023	Change
Revenue	45,563	14,090	31,473
Operating Expenses:			
Research and development expenses	151,406	159,424	(8,018)
Selling, general and administrative expenses	70,446	37,633	32,813
Total operating expenses	221,852	197,057	24,795
Operating Loss	(176,289)	(182,967)	6,678
Other income (expense):			
Interest income	16,881	11,283	5,598
Fair value change - earnout	(37,010)	(266)	(36,744)
Fair value change - warrants	(38,583)	(10,018)	(28,565)
Foreign exchange gains/(losses)	(6,598)	5,058	(11,656)
Loss before tax	(241,599)	(176,910)	(64,689)
Income tax expense	(1)	27	(28)
Loss for the year	(241,598)	(176,937)	(64,661)

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 revenue for a general development cost reimbursement 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 $8.0 million, or 5.0%, to $151.4 million for the year ended December 31, 2024 compared to $159.4 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 $3.1 million increase in personnel expenses.

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

(In thousands of USD)	For the year ended December 31, 2024	2023	Change
Clinical expenses	105,904	106,770	(866)
Non-clinical expenses	1,859	2,917	(1,058)
Personnel expenses	24,019	20,877	3,142
Manufacturing costs	17,188	27,430	(10,242)
Regulatory expenses	2,186	1,297	889
Other research and development costs	250	133	117
Total research and development expenses	**151,406**	**159,424**	**(8,018)**

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 $25.9 million increase in personnel expenses related to selling, general and administrative expenses, of which our share-based compensation arrangements account for $10.3 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 $10.9 million increase in marketing and communication expenses related to startup costs as we begin to build capabilities to support our planned commercial launch of obicetrapib, if approved; and
- a partially offsetting $3.5 million decrease in finance and administration expenses 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.

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 $64.7 million, to $241.6 million for the year ended December 31, 2024 compared to $176.9 million for the year ended December 31, 2023. The individual components of the change are described above.

Comparison of the Years Ended December 31, 2023 and December 31, 2022

Please refer to the section titled "Management Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 for a comparative discussion of our fiscal years ended December 31, 2023 and December 31, 2022.

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 $558.6 million. We expect to continue to incur significant losses for the foreseeable future. We anticipate that our expenses will relate primarily to, and increase substantially as a result of:

- the progress and costs of our discovery, preclinical and non-clinical development;
- the progress and costs of our clinical trials, including costs related to clinical sites, clinical investigators and CROs that are assisting with our sponsored clinical trials, and other research and development activities;
- the costs and timing of obtaining regulatory approval, including the expenses of filing NDAs and MAAs, and the related expenses involved in validating our manufacturing processes;
- the costs associated with any future investigator-sponsored preclinical studies and clinical trials;
- the costs of filing, prosecuting, defending and enforcing any patent applications, claims, patents and other intellectual property rights;
- the costs and timing of obtaining sufficient quantities of our product candidate for clinical trials by establishing production capacities through contracts with 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 an emerging growth company; 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 (the "PIPE 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 in a private placement, an aggregate of 23,460,000 Ordinary Shares at $10.00 per share for gross proceeds of $234.6 million (the "PIPE Financing"). The PIPE Financing closed substantially concurrently with the Business Combination.

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

The following is a summary of cash flows for the years ended December 31, 2024, 2023 and 2022:

	For the year ended December 31,		
(In thousands of USD)	**2024**	**2023**	**2022**
Net cash (used in)/provided by operating activities	(158,564)	(141,218)	10,665
Net cash used in investing activities	(62,848)	(24)	(221)
Net cash provided by financing activities	659,507	8,912	391,905
Foreign exchange differences	(6,802)	5,052	5,248
Cash and cash equivalents at the beginning of the year	340,450	467,728	60,131
Cash and cash equivalents at the end of the year	**771,743**	**340,450**	**467,728**

Net Cash Flows Provided By/Used In Operating Activities

Net cash used in operating activities increased by $17.4 million from $141.2 million in 2023 to $158.6 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 $62.8 million from $0.0 million in 2023 to $62.8 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 $659.5 million in 2024 compared to $8.9 million in 2023, an increase of $650.6 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.

Operating Capital and Capital Expenditure Requirements

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; an 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.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. GAAP. Prior to 2023, we prepared our financial statements in accordance with the IFRS as permitted in the United States based on our qualification as a foreign private issuer under the rules and regulations of the SEC. In connection with the loss of our status as a foreign private issuer effective on January 1, 2024, we, as a domestic filer, prepared our financial statements in accordance with U.S. GAAP. The transition was made retrospectively for all periods from our inception.

The preparation of our consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. We based our estimates on historical experience, known trends and other market-specific or other relevant factors that we believe to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates when there are changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. If actual results differ from our estimates, or to the extent these estimates are adjusted in future periods, our results of operations could either benefit from, or be adversely affected by, any such change in estimate.

See Note 2 to our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for a summary of significant accounting policies and the effect on our consolidated financial statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Our principal financial liabilities consist of trade and other payables lease liability, derivative warrant liabilities and derivative earnout liability. The main purpose of these financial liabilities is to finance our day-to-day operations. Our financial assets consist of prepayments and other receivables and cash, that are derived from our operating activities and funding.

We are exposed to market risk, credit risk and liquidity risk. Our senior management oversees the management of these risks. The Board of Directors reviews and approves 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.

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.

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. Our exposure to the risk of changes in foreign exchange rates relates primarily to cash and trade and other payables denominated in currencies other than our functional currency, the U.S. Dollar. As of December 31, 2024, our net exposure to foreign currency risk was $108.6 million, mainly related 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.

We partly manage our foreign currency risk by selectively holding foreign currency in our cash to offset foreign currency exposures from lease liabilities and trade and other payables. We plan to use this cash to settle future expenses we expect to incur in those foreign currencies.

Other Market Price Risk

As a result of the Business Combination, we have derivative warrant liabilities and a derivative earnout liability which are measured at fair value through profit or loss. As at December 31, 2024, the fair value of the derivative warrant liabilities and the derivative earnout liability were $37.5 million and $44.8 million, respectively. The value of the derivative warrant liability is directly correlated to the market price of a publicly traded Warrant which is traded under the symbol NAMSW. With all other variables held constant, a 1% change in the market price of NAMSW would change the value of the derivative warrant liability by 1% or $0.4 million. The value of the derivative earnout liability is directly correlated to the market price of a publicly traded Ordinary Share which is traded under the symbol NAMS. With all other variables held constant, a 1% change in the market price of NAMS would change the value of the derivative earnout liability by 1% or $0.4 million.

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. We are exposed to credit risk primarily from our treasury activities, including deposits with banks and financial institutions and have limited credit risk exposure from our operating activities. We hold 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.

We perform research and development activities and do not yet have any sales. We are able to reclaim 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.

Item 8. Financial Statements and Supplementary Data

The financial statements of the Company begin on page F-1 of this Annual Report and are incorporated herein by reference.

Selected quarterly financial data is presented below for each quarter in fiscal year 2023 to reflect the Company's material retrospective change due to its conversion from IFRS to U.S. GAAP.

	For the three months ended			
	March 31, 2023	**June 30, 2023**	**September 30, 2023**	**December 31, 2023**
(In thousands of USD, except per share amounts)				
Revenue	8,629	1,717	2,941	803
Operating expenses:				
Research and development expenses	40,420	34,341	43,371	41,292
Selling, general and administrative expenses	8,062	9,858	9,128	10,585
Total operating expenses	48,482	44,199	52,499	51,877
Operating loss	(39,853)	(42,482)	(49,558)	(51,074)
Loss for the period	(42,018)	(38,292)	(47,132)	(49,495)
Net loss per ordinary share				
Basic and diluted	$ (0.51)	$ (0.47)	$ (0.57)	$ (0.60)

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, our principal executive officer and principal financial officer, respectively, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Annual Report on Form 10-K. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is accumulated and communicated to management, including the Chief Executive Officer and the Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Our disclosure controls and procedures have been designed to meet, and management believes that they meet, reasonable assurance standards. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded disclosure controls and procedures were effective as of December 31, 2024.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP.

Our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework established in "Internal Control-Integrated Framework (2013)", issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2024. Our internal control over financial reporting includes policies and procedures that pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and dispositions of assets; provide reasonable assurances that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP and that receipts and expenditures are being made only in accordance with authorizations of management and our directors; and provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Remediation

As discussed in our Form 10-K for the year ended December 31, 2023, our management identified material weaknesses in our internal control over financial reporting related to:

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

Throughout the years ended December 31, 2023 and December 31, 2024, our management, under the oversight of the Audit Committee, executed the previously disclosed remediation plan which included the following measures:

- performed a detailed risk assessment;
- hired additional internal and external accounting resources, including third-party internal control advisors and technical accounting advisors;
- redesigned and documented critical processes and controls associated with internal control over financial reporting;
- designed and maintained formal accounting policies, procedures and controls over the fair presentation of our financial statements;
- implemented a new enterprise resource planning system;
- established proper segregation of duties and management review and approvals across all key business processes, applications and controls over information technology;
- designed, implemented and maintained controls over the preparation and review of journal entries and financial statements;

•designed, implemented and tested the operating effectiveness of internal controls over financial reporting and information technology; and

•implemented management audit tooling to monitor control performance.

Management implemented the majority of the remediation plan in the year ended December 31, 2023 and further tested, strengthened and improved the Internal Control Framework in the year ended December 31, 2024, including performing operating effectiveness testing.

Our management completed operating effectiveness testing over the implemented remediation procedures and controls during the year ended December 31, 2024, and found them to be operating effectively. As a result, management has concluded that the material weaknesses in internal control over financial reporting have been remediated as of December 31, 2024.

Attestation Report of the Registered Public Accounting Firm

Deloitte Accountants B.V., our independent registered public accounting firm, issued an attestation report on our internal control over financial reporting. The report of Deloitte Accountants B.V. is contained in Item 15 of Part IV of this Annual Report.

Changes in Internal Control over Financial Reporting

Other than the remediation activities described above, there were no changes in our internal control over financial reporting during the quarter ended December 31, 2024, identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Securities Trading Plans of Directors and Executive Officers

During the three months ended December 31, 2024, none of our directors or executive officers adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any "non-Rule 10b5-1 trading arrangement.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Current Directors and Executive Officers

The Board of Directors

Set forth below are the names and certain information about each of our directors as of February 26, 2025. The information presented includes each director's age, term and principal occupation. Biographical information for each director is included below the table.

Name	Positions and Offices Held	Year in which Term Expires	Age
Employee Directors			
Michael Davidson, M.D.	Chief Executive Officer, Director	2025	68
John Kastelein, M.D.	Chief Scientific Officer, Non-Executive Director	2027	71
Non-Employee Directors			
William H. Lewis, J.D., M.B.A.	Chair, Non-Executive Director	2028	56
Mark C. McKenna *	Vice Chair, Non-Executive Director	N/A	45
Nicholas Downing, M.D.	Non-Executive Director	2027	39
Wouter Joustra *	Non-Executive Director	N/A	36
Louis Lange, M.D., Ph.D.	Non-Executive Director	2028	76
John W. Smither	Non-Executive Director	2026	72
James N. Topper, M.D., Ph.D.	Non-Executive Director	2025	63
Janneke van der Kamp	Non-Executive Director	2026	49

* 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.

Employee Directors

Dr. Michael Davidson. Michael Davidson, M.D., has served as our Chief Executive Officer and executive director since 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), Silence Therapeutics plc (Nasdaq: SLN) and BioAge Labs, Inc. (Nasdaq: BIOA). Dr. Davidson also serves on the boards of four private biotechnology companies, Sonothera, NanoPhoria Bioscience, Jocasta Neuroscience and Abcentra. 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.

Dr. John Kastelein. John Kastelein, M.D., Ph. D. FESC, has served as our Chief Scientific Officer and non-executive director since 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.

Non-Employee 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 has more than 30 years of executive experience in the pharmaceutical and finance industries both in the United States and internationally. Mr. Lewis has served as President, Chief Executive Officer and director at Insmed Incorporated ("Insmed") since 2012 and has served as Chair of Insmed's board of directors since November 2018. Prior to joining Insmed 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 United States 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.

Dr. Nicholas S. Downing. Nicholas S. Downing, M.D., has served as a member of the Board of Directors since November 2022. Dr. Downing currently serves as a Managing Director of Bain Capital Life Sciences, L.P., a private equity fund that invests in biopharmaceutical, specialty pharmaceutical, medical device, diagnostics and enabling life science technology companies globally, which he joined in 2018. Prior to joining Bain Capital, Dr. Downing was a resident physician at the Brigham and Women's Hospital in Boston, 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 more than 40 articles in 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 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.

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.

Dr. Louis Lange. Louis Lange, M.D., Ph.D., has served as a member of the Board of Directors since 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 private companies Stealth Biotherapeutics Corp., Amygdala Neurosciences, Inc. and Incendia Therapeutics, Inc. Dr. Lange previously served on the board of directors of Audentes Therapeutics, Inc. (sold to Astellas Pharma Inc.) and CymaBay Therapeutics (acquired by Gilead). 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.

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 April 2024, 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.

Dr. James N. Topper. James N. Topper, M.D., Ph.D., has served as a member of the Board of Directors since November 2022. Dr. Topper previously served as FLAC's Chief Executive Officer and Chairman of the FLAC Board of Directors 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 tenure 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), Alpine Immune Sciences (sold to Vertex), Amunix Pharmaceuticals, Inc. (sold to Sanofi), Aptinyx Inc. (Nasdaq: APTX), Calistoga Pharmaceuticals, Inc. (co-founder, sold to Gilead Sciences), Entasis Therapeutics Holdings Inc. (sold to Innoviva), Frazier Lifesciences Acquisition Corporation, Mavupharma (sold to AbbVie), Rempex (sold to The Medicines Company), Incline (co-founder, sold to The Medicines Company), Alnara (sold to Lilly), Portola, Inc. (co-founder, Nasdaq: PTLA), Phathom Pharmaceuticals Inc. (Nasdaq: PHAT), CoTherix, Inc (sold to Actelion), and Threshold Pharmaceutical, Inc. (Nasdaq: THLD). He currently represents Frazier on the boards of companies such as Phathom Pharmaceuticals, Inc. (Nasdaq: PHAT), Lassen Therapeutics, Seraxis Holdings, Inc., Enlaza Therapeutics, Inc., Attovia Therapeutics, Inc., Architect Therapeutics and Serum Detect, 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.

Janneke van der Kamp. Janneke van der Kamp has served as a member of the Board of Directors since April 2023. Ms. van der Kamp currently serves as the Chief Executive Officer of Norgine. Prior to this, she was 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 from 2016 to 2018 and then Head of Pharma Region Europe from 2019 until 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.

Arrangements and Understandings

Drs. Topper and Downing were designated to serve on the Board of Directors by FLAC, and Dr. Davidson, Dr. Kastelein and Dr. Lange were initially designated by NewAmsterdam Pharma pursuant to the terms of the Business Combination Agreement.

Our Executive Officers

The following table sets forth certain information concerning our executive officers as of February 26, 2025.

Name	Position	Age
Michael Davidson, M.D.	Chief Executive Officer	68
Juliette Audet	Chief Business Officer	39
William "BJ" Jones	Chief Commercial Officer	61
John Kastelein, M.D., Ph.D. FESC	Chief Scientific Officer	71
Douglas Kling	Chief Operating Officer	51
Louise Kooij	Chief Accounting Officer	49
Ian Somaiya	Chief Financial Officer	51

Dr. Michael Davidson. Dr. Davidson's biography is included in the section above titled "—The Board of Directors."

Juliette Audet. Juliette Audet has served as the Company's Chief Business Officer since April 2024. Ms. Audet previously served on the NewAmsterdam Pharma board from November 2020 until April 2024. Prior to joining NewAmsterdam Pharma, Ms. Audet was a partner at Forbion from January 2021 until March 2024 and before that, a principal at Forbion from October 2019 until December 2020. Prior to joining Forbion, Ms. Audet was a Principal at Novartis Venture Fund based in Cambridge, Massachusetts from January 2018 until July 2019. Ms. Audet received an M.B.A., with distinction, from Harvard Business School and her M.Sc in physics from EPFL (Lausanne, Swiss Federal Institute of Technology).

William "BJ" Jones. BJ Jones joined the Company in August 2023 as its Chief Commercial Officer where he is responsible for building and leading all commercial and medical affairs functions, including marketing, market access, sales, medical science engagement and enterprise operations. Prior to joining the Company, Mr. Jones most recently served as Chief Commercial Officer, Migraine and Common Diseases of Biohaven Pharmaceuticals Holding Company Ltd., a biopharmaceutical company, from April 2019 to December 2022, where he was responsible for building the company's commercial capability and launching its first FDA-approved product (Nurtec ODT), including through Biohaven's acquisition by Pfizer in October 2022. Prior to Biohaven, Mr. Jones served as Vice President, Head of Sales and Commercial Operations for the general medicine business unit of Takeda Pharmaceutical Company Limited (NYSE: TAK) from January 2016 to March 2019. Mr. Jones currently serves on the board of directors of Apogee Therapeutics, Inc. (Nasdaq: APGE) and Annexon Biosciences, Inc. (Nasdaq: ANNX). Mr. Jones received a B.S. in human factors engineering from the U.S. Air Force Academy, an M.S. in industrial engineering from Texas A&M University and an M.B.A. from the Stanford University Graduate School of Business.

Dr. John Kastelein. Dr. Kastelein's biography is included in the section above titled "—The Board of Directors."

Douglas Kling. Douglas Kling joined the Company in March 2021 as its Chief Operating Officer. Prior to joining NewAmsterdam Pharma, Mr. Kling served as the Senior Vice President of Clinical Development at Corvidia Therapeutics, Inc. from December 2017 until February 2021. From March 2015 until November 2017, Mr. Kling served as the Senior Vice President, Clinical Development at Matinas BioPharma Holdings, Inc. Mr. Kling earned a B.S. from Duke University and an M.B.A. from Rutgers Business School.

Louise Kooij. Louise Kooij joined the Company as its Chief Financial Officer in May 2020. In January 2023, Ms. Kooij was appointed as the Company's Chief Accounting Officer and served in that role until March 2023 when she was appointed Interim Chief Financial Officer. In October 2023 Ms. Kooij was appointed as the Company's Chief Accounting Officer. Ms. Kooij previously spent 18 years working in various finance roles at Genzyme Europe B.V. ("Genzyme"), a multinational biotechnology company. During her tenure at Genzyme, she led the European and Global FP&A team, many European finance projects, the European integration of Genzyme into Sanofi, the integration of acquisitions into Sanofi, the European Business Operations Team as well as the Rare Disease unit in Central and Eastern Europe. Before joining Genzyme, Ms. Kooij worked as a certified auditor at PricewaterhouseCoopers as well as other audit firms for seven years. Since May 2020, Ms. Kooij has also served as an independent consultant in the role of chief financial officer to other private biotechnology start-ups. Ms. Kooij received a master's degree from Nyenrode Business University and her auditing degree from Hogeschool Markus Verbeek.

Ian Somaiya. Ian Somaiya joined the Company in October 2023 as its Chief Financial Officer. Mr. Somaiya has over 25 years of experience in finance and biotechnology. Most recently, Mr. Somaiya served as the Chief Financial and Business Officer at Elucida Oncology, Inc. from November 2021 until July 2023, were he was responsible for fundraising and overall corporate strategy. From April 2018 until November 2021, Mr. Somaiya served as the Chief Financial Officer of TCR^2 Therapeutics, Inc. ("TCR2") where he successfully navigated the company through its initial public offering and two follow-on equity financings, raising more than $350 million in the aggregate. During his tenure at TCR2, Mr. Somaiya led the company's finance and public company reporting functions, as well as the business development and investor relations functions. Prior to joining TCR2, Mr. Somaiya spent over 20 years on Wall Street where he conducted extensive research on more than 100 biotechnology companies across diverse therapeutic areas, technology platforms and stages of development. Mr. Somaiya served as a Managing Director and Head of Biotechnology Research at BMO Capital Markets and served as a Managing Director and Equity Analyst at Nomura Securities Co. Ltd., Piper Jaffray Companies and Thomas Weisel Partners Group, Inc. Mr. Somaiya began his career as a research analyst at Morgan Stanley and Prudential Securities and was recognized as "Best on the Street" by the Wall Street Journal for his

coverage on biotechnology in 2006, 2007 and 2008. Mr. Somaiya received a Bachelor of Arts degree in biology and neuroscience from New York university.

Family Relationships

There are no family relationships among any of our executive officers or directors.

Code of Business Conduct and Ethics

We have adopted 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.

Insider Trading Policies and Procedures

The Company has an insider trading policy and procedures governing the purchase, sale and/or other dispositions of the Company's securities that applies to all directors, officers, employees and certain other persons. It is also the Company's policy to take appropriate steps to comply with applicable federal and state securities laws and regulations, as well as applicable stock exchange listing standards, when the Company engages in transactions in the Company's securities. The Company believes that its insider trading policy and procedures are reasonably designed to promote compliance with insider trading laws, rules and regulations, and listing standards applicable to the Company. A copy of the Company's insider trading policy is filed as Exhibit 19.1 to this Annual Report.

Director Nomination Process

Qualified candidates will be considered without regard to race, color, religion, sex, ancestry, national origin or disability. The nomination and corporate governance committee does not have a formal policy with respect to director candidates recommended by shareholders but may consider candidates it deems qualified from any source. The Board of Directors believes retaining the flexibility to consider a director candidate or ignore a director candidate if it determines doing so is in the best interest of the Company. If the nomination and corporate governance committee approves a candidate for further review they will establish an interview process for the candidate. The nomination and corporate governance committee will also take into consideration the candidate's personal attributes, including, without limitation, personal integrity, loyalty, ability to apply sound and independent business judgment, awareness of a director's vital part in our good corporate citizenship and image, time available for meetings and consultation on our matters and willingness to assume broad, fiduciary responsibility.

Audit Committee

The Audit Committee consists of John W. Smither, William H. Lewis and Mark C. McKenna. Mr. Smither serves as chairperson of the Audit Committee. The Audit Committee assists the Board of Directors in, among other things:

- overseeing the Company's accounting, financial reporting and internal controls processes;
- overseeing the Company's compliance with legal and regulatory requirement, including related to cybersecurity and compliance with the code of business conduct and ethics;
- overseeing the selection, qualifications, independence, and performance of the Company's independent registered public accounting firm; and
- pre-approving of all permitted non-audit services to be performed by the independent registered public accounting firm.

The Audit Committee has the authority to retain independent counsel and advisors to assist in carrying out its responsibilities.

Each member of the Audit Committee is an "independent director," as such term is defined in Nasdaq Rule 5605(a)(2) and meets the criteria for independence set forth in Rule 10A-3(b)(1) under the Exchange Act. The Board of Directors has also determined that each of the Audit Committee members is able to read and understand fundamental financial statements and that at least one member of the Audit Committee has past employment experience in finance or accounting. The Board of Directors has determined that Mr. Smither qualifies as an "audit committee financial expert," as such term is defined in the rules of the SEC.

Item 11. Executive Compensation

Compensation Discussion and Analysis

This Compensation Discussion and Analysis (“CD&A”) describes the philosophy, objectives, process, components and additional aspects of our executive compensation program for the fiscal year ended December 31, 2024. This CD&A is intended to be read in conjunction with the compensation tables that immediately follow this section, which provide historical compensation information for our following named executive officers ("NEOs"):

Name	Position
Michael Davidson, M.D.	Chief Executive Officer
Ian Somaiya	Chief Financial Officer
John Kastelein, M.D., Ph.D. FESC	Chief Scientific Officer
Juliette Audet	Chief Business Officer
Douglas Kling	Chief Operating Officer

Executive Compensation Philosophy and Objectives

We maintain a shareholder-approved, formal, written compensation policy consistent with Dutch law. The compensation policy provides that the amount, level and structure of compensation should contribute to the Company's strategy, long-term interests and sustainability by:

- 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;
- driving strong business performance, promoting accountability and incentivizing 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;
- assuring that the interests of the Company's directors are closely aligned to those of the Company, its business and its stakeholders; and
- ensuring overall market competitiveness of the compensation packages, while providing the Board of Directors sufficient flexibility to tailor the Company's compensation practices on a case-by-case basis, depending on the market conditions from time to time.

To achieve these objectives, the Compensation Committee of the Board of Directors (the “Compensation Committee”) regularly evaluates our executive compensation program to determine components of compensation and establish compensation levels that are appropriate based on each executive’s level of experience, performance, growth potential, job responsibility and criticality of role, and that align with the Company's size and stage.

Executive Compensation Components

Our executive compensation program generally consists of, and is intended to strike a balance among, the following three principal components: base salary, annual performance-based cash bonuses and long-term incentive equity grants. We also provide our executive officers with severance and change-in-control benefits, as well as other benefits available to all our employees, including retirement benefits under the Company’s U.S. 401(k) plan, retirement arrangements for employees in other countries and participation in employee benefit plans. The following chart summarizes the key features and objectives of the three main elements of compensation.

Element	Description	Objectives
Base Salary	•Fixed cash compensation. •Determined based on each executive officer’s role, individual skills, experience, performance, and external market value.	•Provide stable compensation to executive officers, allow the Company to attract and retain skilled executive talent and maintain a stable leadership team.
Short-Term Incentives: Annual Bonus Plan	•Variable cash compensation based on the level of achievement of pre-determined annual corporate goals and personal performance.	•Promote and reward the achievement of key annual strategic, business and operational goals.

Long-Term Incentives: Equity-Based Compensation	•Variable equity-based compensation. •Share options: Right to purchase shares at a price equal to the share price on the grant date.	•Motivate and reward achievement of multi-year strategic goals and delivery of sustained long-term value to shareholders, as well as attract and retain executive officers.

Compensation Program Governance

The Compensation Committee assesses the effectiveness of our executive compensation program from time to time and reviews risk mitigation and governance matters, which includes maintaining the following best practices:

	What We Do	
☑	Pay for Performance	The majority of total executive compensation is variable and at-risk.
☑	Balance Short- and Long-Term Compensation	The allocation of incentives among annual cash incentives and long-term equity incentives does not over-emphasize short-term performance at the expense of achieving long-term goals.
☑	Combination of Balanced Performance Metrics	We use a diverse set of milestone performance metrics in our annual performance bonus plan to ensure that no single measure affects compensation disproportionately.
☑	Independent Compensation Consultant	The Compensation Committee has engaged an independent compensation consultant to provide information and advice for use in Compensation Committee decision-making.
☑	Peer Data	We develop a peer group of companies based on industry, development stage, therapeutic focus, research and development expense, market capitalization, employee headcount, and number of years as a public company to reference for compensation decisions.
☑	Clawback	We maintain a clawback policy compliant with SEC and Nasdaq rules.
☑	Double Trigger Change-in-Control Provisions	We entered into agreements with each of the NEOs that provide certain financial benefits if there is both a change in control and a termination of employment (a "double trigger"). A change in control alone would not trigger cash severance pay.

	What We Don't Do	
✗	No Hedging or Pledging of Company Securities	We prohibit officers and non-employee directors from engaging in hedging, pledging or short sale transactions in Company securities.
✗	No Perks	We do not provide material perquisites to executive officers.
✗	No Excise Tax Gross-Ups	We do not provide excise tax gross-ups.
✗	No Share Options Below Fair Market Value	We do not grant share options with an exercise price below fair market value.
✗	No Guaranteed Compensation	We do not have agreements with our NEOs that provide any guarantees relating to base salary increases or the amounts of any annual cash incentive awards or long-term equity awards.

✗	No Special Retirement Benefits	We do not provide defined benefit pension arrangements or post-retirement health coverage for our executive officers or employees. Our NEOs and other executives are eligible to participate in our 401(k) plan (U.S.) or personal pension plan on the same basis as our other employees.
✗	No Share Option Repricing	We do not permit repricing of share options or share appreciation rights without shareholder approval.

Compensation Determination Process

Role of our Shareholders

Our shareholders have adopted a formal, written compensation policy in accordance with Dutch law. Changes to the compensation policy will require a vote of the General Meeting by simple majority of votes cast. The Board of Directors and the Compensation Committee determine the compensation of individual directors and executive officers with due observance of the compensation policy to the extent applicable.

We did not consider the results of any shareholder advisory vote on the 2024 compensation of our NEOs, as no such vote was required due to our status as an "emerging growth company" as of December 31, 2024.

Role of the Compensation Committee

The Compensation Committee establishes the compensation philosophy and objectives (in accordance with the compensation policy), determines the structure, components and other elements of executive compensation, and reviews and approves the compensation of the NEOs or recommends it for approval by the Board of Directors. The Compensation Committee structures the executive compensation program to accomplish its articulated compensation objectives in light of the compensation philosophy described above.

The Compensation Committee annually reviews compensation policies and procedures to determine if any updates are needed. The Compensation Committee also approves, or recommends to the Board of Directors for approval, the corporate objectives associated with our annual performance-based cash incentive program, as well as assessing the Company's performance against those corporate objectives after the end of the year or making a recommendation to the Board of Directors as to the extent to which the Company has met those corporate objectives.

The Compensation Committee meets periodically throughout the year to manage and evaluate our executive compensation program, and generally determines executive compensation on an annual basis, typically at the beginning of each fiscal year; however, decisions may occur during the year for new hires, promotions or other special circumstances as the Compensation Committee determines appropriate.

Role of the CEO and Management

The Compensation Committee generally seeks the input of our Chief Executive Officer ("CEO") when discussing the performance of, and compensation for, our executive officers, including the NEOs other than the CEO. Our CEO is instrumental in developing both our annual and long-term strategic objectives and goals, which are reviewed and approved by the Compensation Committee and the Board of Directors. Our CEO is also instrumental in providing perspective on our performance against those goals.

Our CEO reviews the performance of the other executive officers, including the other NEOs, annually and presents his conclusions to the Compensation Committee. Our CEO then provides corresponding compensation recommendations, including as to base salary adjustments, annual performance-based cash compensation targets and payouts, and equity awards. The Compensation Committee considers the CEO's input as one factor in its deliberations to determine the compensation of our executive officers, including the other NEOs. The Compensation Committee gives significant weight to the recommendations of the CEO in light of his greater familiarity with the day-to-day performance of his direct reports and the importance of incentive compensation in driving the execution of managerial initiatives developed and led by the CEO.

While the CEO may attend Compensation Committee meetings, the CEO may not be present during voting or deliberations on his compensation and does not play a role in determining his compensation.

In addition, other members of management may attend Compensation Committee meetings to provide background information or advice, or to answer questions posed by members of the Compensation Committee, including with respect to the financial, accounting, tax and retention implications of various compensation decisions.

Role of the Independent Compensation Consultant

The Compensation Committee recognizes that there is value in procuring independent, objective expertise in connection with fulfilling its duties, and pursuant to its charter, the Compensation Committee has the authority to select and retain advisors to assist it with carrying out its duties and responsibilities.

The Compensation Committee has engaged the services of an independent compensation consultant, the Human Capital Solutions practice of Aon plc ("Aon"), to assist it in connection with making executive compensation decisions. The Compensation Committee has worked with Aon to develop a peer group, to provide a competitive market analysis of the base salary, annual performance-based cash incentive awards and long-term incentive compensation of our executive officers compared against the peer group, and to review other market practices and trends with respect to executive compensation.

The Compensation Committee annually assesses the independence of Aon pursuant to SEC and Nasdaq rules. In 2024, the Compensation Committee assessed the independence of Aon consistent with Nasdaq listing standards and concluded that the engagement of Aon does not raise any conflict of interest.

While the Compensation Committee took into consideration the review and recommendations of Aon when making decisions about our executive compensation program, ultimately, the Compensation Committee made its own independent decisions in determining our executives' compensation.

Consideration of Comparative Market Data

The Compensation Committee believes that obtaining relevant market and benchmark data is important to making determinations about executive compensation. This information provides a solid reference point and helpful context for making compensation decisions, even though, relative to other companies, there are differences and unique aspects of the Company.

With Aon's assistance and input, the Compensation Committee annually adopts a peer group of companies that it uses as a reference group to provide a broad perspective on competitive pay levels and practices.

In doing so, the Compensation Committee seeks to approve a peer group that is representative of the sector in which we operate and includes companies within an appropriate defined range in terms of key attributes.

In October 2023, the Compensation Committee determined that our peer group for determining the compensation of our NEOs in 2024 would consist of Phase 2 and Phase 3 biopharmaceutical/biotechnology companies. In general, the selection criteria consisted of the following:

- market capitalizations between one-third and three times the market capitalization of the Company;
- annual revenues less than $100 million;
- fewer than 150 employees; and
- preference given to companies that went public within the last five years.

Based on these criteria, the peer group for setting 2024 compensation consisted of the following 24 companies:

4D Molecular Therapeutics, Inc.	Humacyte, Inc.	PMV Pharmaceuticals, Inc.
89bio, Inc.	IDEAYA Biosciences, Inc.	Replimune Group, Inc.
Akero Therapeutics, Inc.	Immunovant, Inc.	Scholar Rock Holding Corporation
Belite Bio, Inc.	Inhibrx, Inc.	Structure Therapeutics Inc.
Cogent Biosciences, Inc.	Keros Therapeutics, Inc.	Tarsus Pharmaceuticals, Inc.
Crinetics Pharmaceuticals, Inc.	Krystal Biotech, Inc.	Ventyx Biosciences, Inc.
Cullinan Oncology, Inc.	Madrigal Pharmaceuticals, Inc.	Vera Therapeutics, Inc.
Erasca, Inc.	Pliant Therapeutics, Inc.	Viking Therapeutics, Inc.

The Compensation Committee utilizes the compensation of executive officers of the companies in this peer group as one reference point in the compensation-setting process along with various other factors, such as the executive's performance, experience, and competitive market conditions.

Additionally, when considering the establishment of 2024 compensation levels for our NEOs, the Compensation Committee, upon recommendation from Aon, supplemented the 2024 peer group long-term incentive market data with data derived from the Radford 2023 Global Life Science Survey for public pre-commercial biopharma companies with under 150 employees. This survey data was used to obtain a general understanding of the compensation practices of companies similar to ours at the time.

The Compensation Committee believes that the compensation practices of our peer group, together with the data derived from the Radford 2023 Global Life Science Survey, provided us with appropriate compensation reference points for evaluating and determining the compensation of our NEOs during 2024.

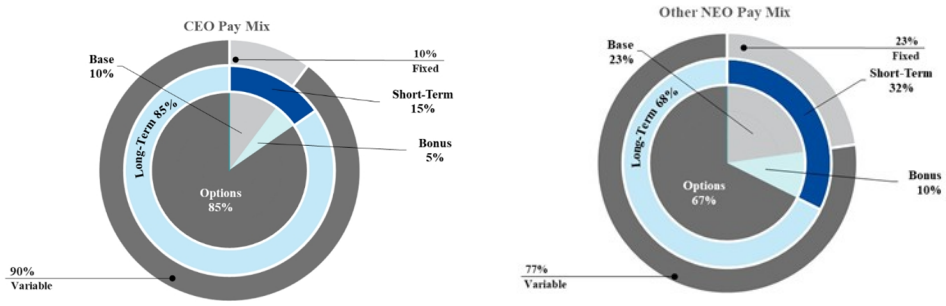
2024 Executive Compensation Program

Our executive compensation program generally consists of, and is intended to strike a balance among, the following three principal components: base salary, annual performance-based cash bonus, and long-term incentive equity compensation.

CEO and NEO Pay Mix

Though the Compensation Committee has not adopted any formal or informal policies or guidelines that specify the allocation of compensation between these three elements, consistent with our "pay-for-performance" philosophy, the Compensation Committee has determined that NEO compensation packages must include an emphasis on and substantial portion of variable, at-risk pay while ensuring adequate base salary to attract and retain talent. The Compensation Committee considers compensation to be at-risk if it is subject to performance-based payment or vesting conditions or if its value depends on share price appreciation.

Our executive compensation is linked strongly to the performance of the business, with a majority of annual target compensation being variable and at-risk. In 2024, 90% of the total target compensation for the CEO was at-risk and 77% of the total target compensation for all other NEOs was at-risk. The following pay mix pie chart graphics illustrate our emphasis on variable, at-risk pay and long-term incentives.



The percentages of target total direct compensation as calculated above are based on the annualized 2024 base salary, the 2024 annual cash incentive compensation opportunity (assuming achievement at the target level), and the grant date fair value of the annual option grants to NEOs. Each compensation element is described in this section and outlined in more detail in the Summary Compensation Table and Grants of Plan-Based Awards table below.

Base Salary

We provide our executive officers with fixed cash compensation in the form of a base salary. In establishing base salaries, the Compensation Committee exercises its judgment and discretion and considers several factors, including the performance of the individual executive officer, the officer's potential to contribute to our long-term strategic goals, the officer's role and scope of responsibilities within our Company, individual experience and skills, the officer's compensation as compared to similarly situated executives at comparable companies in our peer group, competitive market dynamics for the position, and (with respect to other NEOs) the input of our CEO. None of our NEOs is currently party to an employment agreement or other agreement or arrangement that provides for automatic or scheduled increases in base salary.

Annual base salaries for our NEOs for the positions they held as of December 31, 2024, as compared with their annual base salaries as of December 31, 2023, were as follows:

NEO	2024 Base Salary ($)	2023 Base Salary ($)	% Change
Michael Davidson, M.D.	621,300	569,000	9%
Ian Somaiya (1)	468,000	450,000	4%
John Kastelein, M.D., Ph.D. FESC (2)	486,046	459,346	6%
Juliette Audet (3)	429,672	N/A	N/A
Douglas Kling	500,000	N/A	N/A

(1)The 2023 Base Salary for Mr. Somaiya represents his annualized compensation. Mr. Somaiya was paid a pro rata amount for the portion of the year he served, which started from October 2023.

(2)Dr. Kastelein is paid his salary and bonus in Euros. The table above presents Dr. Kastelein's compensation converted into USD at a rate of $1.0824 per Euro, which was the average exchange rate as published by the European Central Bank for 2024.

(3)Ms. Audet is paid her salary and bonus in Swiss francs. The table above presents Ms. Audet's annualized compensation converted into USD at a rate of $1.1337 per Swiss franc, based upon a nine-month average rate during the period from April 1, 2024 through December 31, 2024.

Annual Performance-Based Cash Bonus

The annual cash incentive bonus plan (the "Annual Bonus Plan") is a cash-based plan that rewards executive officers for the achievement of key short-term objectives. The structure of the Annual Bonus Plan incentivizes executive officers to achieve research, clinical, operational, and organizational results that the Compensation Committee views as critical to the execution of our business strategy.

For the NEOs, the amount of the payout, if any, under the Annual Bonus Plan is based on operational performance as well as individual performance. The Annual Bonus Plan gives considerable weight to achievement of key corporate and individual goals, while providing the Compensation Committee with the ability to exercise its best judgment in determining the overall level of achievement of such goals.

Target Opportunities. The Compensation Committee determines the target cash incentive opportunity available to each NEO by taking the individual's annual base salary in effect for the year and multiplying it by the individual's target incentive percentage. Among other factors, the target incentive percentages are determined with reference to the peer group company percentages of salary for the respective positions and the proportion of total direct compensation represented by the annual cash incentive. For 2024, our NEOs had the following annual cash bonus targets:

NEO	2024 Target Annual Bonus Opportunity as a % of Base Salary
Michael Davidson, M.D.	50%
Ian Somaiya	45%
John Kastelein, M.D., Ph.D. FESC	40%
Juliette Audet	40%
Douglas Kling	40%

Corporate Performance Goals. As a pre-commercial biopharmaceutical company, we do not have material revenue or profits at this stage, and our success is measured by achievement of research and development milestones and other key strategic and operational goals.

In evaluating corporate performance, the Compensation Committee considered our achievement against the 2024 corporate goals as follows:

- Clinical development goals to progress our product candidate (relative weighting 40%, or plus 75% upon achievement of stretch goals);
- Chemistry, Manufacturing and Controls goals relating to on-time supply for clinical trials and launch readiness (5%);
- Finance goals of assuring adequate funding for current activities and a reasonable runway (20%);
- Intellectual Property, Operations and Business Development goals related to patents, trademarks and regulatory requirements, hiring for new key positions, and initiating various business development activities (15%, or plus 25% upon achievement of stretch goals); and
- Commercial / Medical Affairs goals, including the development and execution of launch plan in multiple markets (20%).

Corporate Performance Goals and Related Payouts. If we do not achieve an objective of corporate performance, there is no corresponding amount to be included in the payout related to that element. If we achieve the objective, the Compensation Committee will authorize a payout of the portion of the overall opportunity allocated to that element; if we exceed the objective by achieving a stretch goal, the Compensation Committee may, in its discretion, authorize a higher payout, but the total payout will not exceed 200% of an executive's overall target incentive.

2024 Achievement of Corporate Goals. In January 2025, the Compensation Committee met to consider how the Company had performed against corporate performance goals. While the Compensation Committee considered management's views regarding their 2024 achievements, the Compensation Committee made an independent determination regarding corporate performance, which included consideration of the following:

Clinical Research

In 2024, we announced updated clinical results for the following:

•In April, we announced that we met the enrollment target for PREVAIL, the Phase 3 clinical trial evaluating obicetrapib in adult patients with a history of ASCVD, whose LDL-C is not adequately controlled, despite being on maximally tolerated lipid-lowering therapy. Driven by strong patient and physician interest globally, we extended enrollment to the end of April and randomized over 9,500 patients.

•In May, we announced the initiation of REMBRANDT, a Phase 3 clinical trial evaluating obicetrapib and ezetimibe against placebo on coronary atherosclerotic plaque characteristics in adults with or at high-risk for atherosclerotic cardiovascular disease.

•In July, we announced positive statistically significant results from BROOKLYN, the first of two pivotal Phase 3 trials of obicetrapib. This trial evaluated the efficacy and safety of 10 mg obicetrapib compared to placebo and showed that obicetrapib has a substantial and rapid effect on LDL levels. Obicetrapib was also observed to be well tolerated, with safety results comparable to placebo and no increase in blood pressure.

•In November, we announced positive topline results from TANDEM, the Phase 3 trial evaluating obicetrapib and ezetimibe fixed-dose combination. These results will support our global regulatory filings for the 10 mg obicetrapib and 10 mg ezetimibe fixed-dose combination in adult patients with HeFH and/or ASCVD or multiple ASCVD risk factors, which will potentially offer a simple, once-daily treatment capable of significantly reducing LDL-C and improve cardiovascular outcomes.

•In December, we announced positive topline data from a pivotal Phase 3 BROADWAY clinical trial evaluating obicetrapib in patients with atherosclerotic cardiovascular disease and/or heterozygous familial hypercholesterolemia.

Corporate

•In February, we completed an upsized public offering of 5,871,909 ordinary shares and 4,736,841 pre-funded warrants, generating net proceeds of $190.0 million after deducting underwriting discounts and commissions and offering expenses payable by the Company. The offering attracted several new and existing investors.

•In April, we appointed Juliette Audet as Chief Business Officer.

•In June, we announced the USPTO issued U.S. Patent No. 12,006,305, titled “Salts of Obicetrapib and Processes for their Manufacture and Intermediates Thereof.” The patent contains claims covering amorphous obicetrapib hemicalcium, the solid form that will be used in the Company’s products and will be listed in the FDA’s “Orange Book” as a drug substance patent, if approved. The issuance of this composition of matter patent provides intellectual property protection for obicetrapib until July 2043.

•In December, we completed an upsized public offering of 14,667,347 ordinary shares and 4,882,653 pre-funded warrants, generating net proceeds of $453.4 million after deducting underwriting discounts and commissions and offering expenses payable by the Company. The offering attracted several new and existing investors.

Individual Performance. In determining Annual Bonus Plan payouts, the Compensation Committee also evaluated the individual performance of our NEOs. The Compensation Committee views the inclusion of individual performance as an important component of the annual cash bonus plan because it motivates the NEOs for individual performance, even if overall corporate performance is lower. In assessing the individual performance of our NEOs, the Compensation Committee, with the input of our CEO for the non-CEO NEOs, considered each such officer’s individual contributions to the achievement of our 2024 goals, and the officer’s individual performance in helping to execute on our strategic and operating initiatives.

Overall Payouts. Based on the assessment described above, the Compensation Committee recommended, and the Board of Directors determined, that the Company’s corporate performance exceeded the 2024 goals. The Compensation Committee determined an overall 2024 performance level, as determined with reference to both corporate performance and individual performance. The amounts of the annual bonus awards for 2024 were determined as follows:

NEO	Base Salary ($)	Target Annual Bonus %	Target Incentive Amount ($)	Overall Performance %	Payout ($)
Michael Davidson, M.D.	621,300	50%	310,650	160%	497,040
Ian Somaiya	468,000	45%	210,600	175%	368,550
John Kastelein, M.D., Ph.D. FESC (1)	486,046	40%	186,946	175%	327,031
Juliette Audet (2)(3)	424,480	40%	169,792	150%	188,406
Douglas Kling	500,000	40%	200,000	200%	399,974

(1)The 2024 target incentive and payout amounts for Mr. Kastelein have been converted from Euros to USD at an exchange rate of 1 Euro to $1.0404 USD.

(2)The 2024 target incentive and payout amounts for Ms. Audet have been converted from Swiss francs to USD at an exchange rate of 1 Swiss franc to $1.1047 USD.

(3)The payout amount for Ms. Audet is pro rata for the portion of the year that she served, which was the last nine months.

Equity-Based Incentive Awards

The third and largest component of the executive compensation program is long-term equity incentives. The Compensation Committee designed the long-term incentive opportunity for the NEOs to motivate and reward executive officers to achieve multiyear strategic goals and deliver sustained long-term value to shareholders.

We believe that equity awards provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our shareholders. Long-term equity incentives also promote retention because executive officers will only receive value if they remain employed by us over the required term.

Grants to our NEOs and other employees are made at the discretion of the Compensation Committee and are generally made upon commencement of employment, promotion or annually during the first quarter of each year. We believe that our equity awards are an important retention tool for our executive officers, as well as for our other employees.

We have used stock option grants as our primary equity vehicle because we believe that they are an effective means by which to align the long-term interests of our executive officers with those of our shareholders. Among companies that are similar to ours in terms of stage of development, options are very common as the form of equity awards. Share options can motivate stock price appreciation over the long term because they deliver value only if the stock price increases. The use of share options also can provide tax and other advantages to our executive officers relative to other forms of equity compensation.

In determining the number of options to be granted to an NEO, the Compensation Committee takes into account equally both the range of long-term incentive award values granted to executive officers at the companies in the peer group and the range of grant size as a percent of the companies in the peer group.

The annual option incentive awards granted to our NEOs are set forth in the table below:

NEO	Share Options (#)	Share Options ($)(1)
Michael Davidson, M.D.	1,039,939	5,347,060
Ian Somaiya	80,000	411,337
John Kastelein, M.D., Ph.D. FESC	500,000	2,570,852
Juliette Audet	250,000	2,602,746
Douglas Kling	323,771	1,664,729

(1)The amounts reflect the grand date fair value of the options granted.

The exercise price of all share option awards to NEOs is equal to the closing price of our shares on the date of the grant, and all share options granted in 2024 have a ten-year term. The options are subject to time-based vesting, with 25% of the total number of shares underlying the award vesting on the first anniversary of the date of grant and thereafter in equal monthly installments for 36 months, subject to the applicable NEO's continued service through each such vesting date.

Additional Elements of Compensation

Employee Benefits

Our NEOs are eligible to participate in all our employee benefit plans, such as medical, dental, vision, group life, short and long-term disability and our 401(k) plan for U.S. employees, in each case on the same basis as other employees, subject to applicable laws. Under our 401(k) plan, the Company currently makes matching contributions of 100% of the first 3% and then 50% of the next 2% of employee contributions. We believe these benefits are important to attracting and retaining experienced employees, including our executives.

Ms. Audet resides in Switzerland and is employed by the Company in Switzerland. In 2024, the Company made contributions to Ms. Audet’s statutory Swiss pension plan account in accordance with Swiss law.

Perquisites

We do not provide material perquisites to our executive officers.

Severance and Change in Control Arrangements

We have entered into employment agreements with all our NEOs that provide for at-will employment without any specific term. Each of the agreements sets forth the NEO’s severance benefits payable upon a qualifying termination of employment or change in control of the Company. The “Potential Payments Upon Termination or Change in Control” section below describes and quantifies the severance and other benefits potentially payable to the NEOs in further detail.

These agreements provide for a combination of a cash severance payment, continued health benefits and acceleration of vesting on outstanding equity awards in specified circumstances. Acceleration of vesting is subject to a “double trigger” arrangement, meaning that

vesting acceleration occurs only in the event of a change in control of the Company in connection with or followed by a termination of employment without cause by us, or with good reason by the NEO.

Given the industry in which we participate and the range of strategic initiatives that we may explore, we believe reasonable and competitive severance and change-in-control payment and benefit arrangements are an essential element of our executive compensation package and assist us in recruiting and retaining a talented executive team. We also believe such payments and benefits are in the best interests of our shareholders because they incentivize senior executives to continue to strive to achieve shareholder value in connection with change-in-control situations, particularly where the possibility of a change-in-control and the related uncertainty may lead to the departure or distraction of senior executives to the detriment of our Company and our shareholders.

We do not provide any excise tax gross ups in connection with severance paid upon termination without cause or relating to a change-in-control transaction. All change-in-control cash payments are structured to be on a "double-trigger" basis, requiring a termination without cause by us, or with good reason by the NEO, in connection with the change-in-control transaction.

Additional Compensation Policies and Practices

Clawback Policy

In 2023, the Compensation Committee of our Board adopted our Incentive Compensation Recoupment Policy (the "Clawback Policy"), designed to comply with Rule 10D-1 of the Exchange Act and Nasdaq Listing Rule 5608, which provides for recoupment of incentive compensation in the event of an accounting restatement resulting from material noncompliance with financial reporting requirements under the relevant securities laws. The policy applies to our current and former executive officers. Compensation that is granted, earned or vested based wholly or in part upon attainment of a Financial Reporting Measure (as defined in the Clawback Policy) that is determined to have been paid erroneously given the restatement is subject to recoupment.

Equity Granting Practices

The Compensation Committee does not grant stock options or similar equity awards during periods in which there is material nonpublic information about our Company, including (1) outside a "trading window" established in connection with the public release of quarterly results information or (2) at any time during the four business days prior to or the one business day following the filing of our periodic reports or the filing or furnishing of a Form 8-K that discloses material nonpublic information. The Compensation Committee does not take material nonpublic information into account when determining the timing and terms of equity awards. Stock options may occasionally be awarded on an off-cycle basis, including to new hires. The Company has not timed the disclosure of material nonpublic information to affect the value of executive compensation.

Anti-Hedging and Anti-Pledging Policies

We have a policy that prohibits our executive officers, directors and other employees from engaging in short sales, transactions in put or call options, or other inherently speculative transactions with respect to our shares. In addition, our insider trading policy prohibits pledging Company securities as collateral for a loan or ownership of Company securities in a margin account. Any violation of these policies may result in disciplinary action, including dismissal for cause.

Tax Considerations; Section 162(m)

When reviewing compensation matters, the Compensation Committee considers the anticipated tax consequences to us (and, when relevant, to our executive officers) of the various payments under our compensation programs. Section 162(m) of the Code generally disallows a tax deduction for any publicly held corporation for individual compensation of more than $1.0 million to certain executive officers in any taxable year. The Compensation Committee may provide compensation to executive officers that may not be tax deductible if it believes that providing that compensation is in the best interests of our Company and its shareholders.

Accounting Policies for Stock-Priced Compensation

We follow the Financial Accounting Standards Board's Accounting Standards Codification Topic 718 ("ASC 718") for our stock-based compensation awards. ASC 718 requires companies to calculate the grant date "fair value" of their stock-based awards using a variety of assumptions. ASC 718 also requires companies to recognize the compensation cost of their stock-based awards in their income statements over the period that an employee is required to render service in exchange for the award. Grants of share options under our equity incentive award plans are accounted for under ASC 718. Our Board or Compensation Committee will regularly consider the accounting implications of significant compensation decisions, especially in connection with decisions that relate to our equity incentive award plans and programs.

Report of the Compensation Committee on Executive Compensation

This Compensation Committee Report shall not be deemed to be incorporated by reference into any filing made by the Company under the Securities Act or the Exchange Act, notwithstanding any general statement contained in any such filing incorporating this Annual Report by reference, except to the extent the Company incorporates such Report by specific reference.

The Compensation Committee has reviewed and discussed the Compensation Discussion and Analysis with the management of the Company. Based on this review and these discussions, we have recommended to the Board of Directors that the Compensation Discussion and Analysis be included in the Company's Annual Report on Form 10-K and the Company's proxy statement.

The preceding report has been furnished by the following members of the Compensation Committee:

Louis Lange, M.D., Ph.D. – Chair
William Lewis, J.D., M.B.A.
Mark McKenna

Executive Compensation Tables

Summary Compensation Table

The following table sets forth information required under SEC rules concerning the compensation paid to our NEOs in respect of fiscal years ended December 31, 2024 and 2023.

Name and Principal Position	Year	Salary(1) ($)	Bonus ($)	Option Awards (2) ($)	Non-Equity Incentive Plan Compensation (3) ($)	All Other Compensation (4) ($)	Total ($)
Michael Davidson, M.D.	2024	621,300		5,347,060	497,040	3,897	6,469,297
Chief Executive Officer	2023	569,000	313,000	4,923,558			5,805,558
Ian Somaiya	2024	468,000		411,337	368,550	4,688	1,252,575
Chief Financial Officer	2023	90,576	40,000	3,422,493			3,553,069
John Kastelein, M.D., Ph.D. FESC	2024	486,046		2,570,852	327,031		3,383,929
Chief Scientific Officer	2023	459,346	218,412	2,300,813			2,978,571
Juliette Audet (5)	2024	322,254		2,602,746	188,406	25,068	3,138,474
Chief Business Officer	2023						
Douglas Kling	2024	499,968		1,664,729	399,974	13,800	2,578,471
Chief Operating Officer	2023						

(1)The U.S. dollar amount reported for 2024 for Dr. Kastelein from Euros ("EUR") using the 2024 average exchange rate of $1.0824 per EUR. The U.S. dollar amount reported for 2024 for Ms. Audet were converted from Swiss Francs ("CHF") using the average exchange rate of $1.1337 per CHF during the 9-month period starting April 1, 2024, through December 31, 2024.

(2)Represents the aggregate fair value of awards on the date they were granted in accordance with ASC Topic 718. See the Notes to the Consolidated Financial Statements included herein for the assumptions used to calculate grant date fair value.

(3)The amounts reported are comprised of amounts paid in respect of our annual performance-based cash bonus plan, as determined by the Compensation Committee. Payments pursuant to the plan are generally made early in the year following the year in which they are earned. The U.S. dollar amount reported for 2024 for Ms. Audet were converted from CHF using the average exchange rate of $1.1337 per CHF during the 9-month period starting April 1, 2024, through December 31, 2024.

(4)The amounts reported in this column represent the amount of fees Dr. Davidson received for service on the Board of Directors in 2024, the amounts of Company contributions under our 401(k) plan for Messrs. Somaiya and Kling, and the Company pension contribution for Ms. Audet. The Company pension contribution for Ms. Audet was converted from CHF to U.S. dollars using the average exchange rate of $1.1337 per CHF during the 9-month period starting April 1, 2024, through December 31, 2024.

(5)Ms. Audet joined the Company as Chief Business Officer in April 2024. Her compensation included in the table above represents her pro-rata base salary and bonus and her initial equity award.

Grants of Plan Based Awards

The following table sets forth certain information regarding grants of plan-based awards to our NEOs during the year ended December 31, 2024:

Name	Estimated Future Payouts Under Non-Equity Incentive Plan Awards (1) Threshold ($)	Target ($)	Maximum ($)	Option Awards: Securities Underlying Options (#)(2)	Exercise or Base Price of Option Awards ($/Sh)	Grant Date Fair Value of Stock and Option Awards ($)
Michael Davidson, M.D.	—	310,650	621,300	1,039,939	11.17	5,347,060
Ian Somaiya	—	210,600	421,200	80,000	11.17	411,337
John Kastelein, M.D., Ph.D. FESC	—	194,418	388,837	500,000	11.17	2,570,852
Juliette Audet	—	171,869	343,738	250,000	21.37	2,602,746
Douglas Kling	—	200,000	400,000	323,771	11.17	1,664,729

(1)The amounts disclosed in these columns reflect the threshold, target and maximum annual cash incentive opportunities of our NEOs. The amounts of the annual cash incentive opportunities are set based on a percentage of the base salary for the calendar year by each NEO. Below or at threshold performance results in 0% payout. See "Compensation Discussion and Analysis—Compensation Program Components—Annual Performance-Based Cash Bonus" for a detailed description of our annual cash incentive plan, including the criteria for determining the amounts payable. Actual annual cash incentive plan results are reported in the "Non-Equity Incentive Plan Compensation" column of the Summary Compensation Table. The maximum payout is 200% of target.

(2)Amounts disclosed in this column reflect the number of shares underlying share option awards granted to our NEOs. The exercise price of all share option grants to NEOs is equal to the closing price of our shares on the date of the grant, and all share options granted in 2024 have a ten-year term. The options are subject to time-based vesting, with 25% of the total number of shares underlying the award vesting on the first anniversary of the date of grant and thereafter in equal monthly installments for 36 months, subject to the applicable NEO's continued service through each such vesting date.

Outstanding Equity Awards at Fiscal Year-End Table

The table below reflects outstanding equity awards held by our NEOs as of December 31, 2024.

Name	Grant Date		Number of Securities Underlying Unexercised Options Exercisable (#)	Unexercisable (#)	Option Exercise Price	Option Expiration Date
Michael Davidson, M.D.	11/22/2022	(1)(2)	989,267		1.21	7/6/2031
	11/22/2022	(2)	1,271,125	1,169,413	10.00	11/22/2032
	1/1/2023	(2)	489,463	532,022	10.90	1/1/2033
	1/1/2024	(2)		1,039,939	11.17	1/1/2034
Ian Somaiya	11/1/2023	(2)	240,536	584,161	9.26	11/1/2033
	1/1/2024	(2)		80,000	11.17	1/1/2034
John Kastelein, M.D., Ph.D. FESC	11/22/2022	(1)(2)	970,229		1.21	7/6/2031
	11/22/2022	(2)	506,125	465,601	10.00	11/22/2032
	1/1/2023	(2)	228,732	248,615	10.90	1/1/2033
	1/1/2024	(2)		500,000	11.17	1/1/2034
Juliette Audet	4/1/2024	(2)		250,000	21.37	4/1/2034
Douglas Kling	11/22/2022	(1)(2)	407,138	19,007	1.21	7/6/2031
	11/22/2022	(2)	345,225	317,593	10.00	11/22/2032
	1/1/2023	(2)	138,589	144,624	10.90	1/1/2033
	1/1/2023	(3)		5,996	10.90	1/1/2033
	1/1/2024	(2)		323,771	11.17	1/1/2034

(1)The exercise price of the option is Euro 1.16392 and has been converted into USD in the table above at a rate of $1.0389 per Euro, which was the exchange rate as of December 31, 2024 as published by European Central Bank.

(2)One-fourth of the shares subject to the option vested on the one-year anniversary of the vesting start date, and the remaining vest in 36 substantially equal monthly installments thereafter.

(3)All shares subject to the option vest on the fourth anniversary of the vesting start date.

Option Exercises and Stock Vested Table

The following table sets forth information concerning options exercised by our NEOs during the fiscal year ended December 31, 2024. No stock awards held by our NEOs vested in 2024.

	Option Awards	
Name	Number of Shares Acquired on Exercise (#)(1)	Value Realized on Exercise ($)(2)
John Kastelein, M.D., Ph.D. FESC	201,673	4,094,829

(1)The amounts shown in this column represent the number of shares underlying the stock options exercised during 2024.

(2)The amounts shown in this column reflect the value realized upon exercise of stock options, as calculated based on the price of our shares on the exercise date less the exercise price, multiplied by the number of shares underlying the stock options exercised.

Potential Payments Upon Termination or Change-in-Control

We have entered into employment agreements with each of our NEOs. These agreements set forth the initial terms and conditions of each executive's employment with us, including base salary, target annual bonus opportunity, standard employee benefit plan participation, and for all NEOs, severance benefits upon a qualifying termination of employment or change-in-control of the Company.

Employment Agreement with Michael Davidson, M.D.

We entered into an employment agreement with Dr. Davidson, our Chief Executive Officer, on January 25, 2023 (the "Davidson Agreement"). Pursuant to the Davidson Agreement, in the event Dr. Davidson's employment is terminated by the Company without Cause (as defined in the Davidson Agreement) or by him for Good Reason (as defined in the Davidson Agreement), we would be required, subject to customary conditions, to pay Dr. Davidson, in addition to certain Accrued Obligations (as defined in the Davidson Agreement), an amount equal to 12 months of his base salary, any bonus earned or payable and a pro-rated bonus for the calendar year in which the termination occurred, and premium reimbursement equal to the monthly employer contribution that the Company would have made to provide health coverage under the Consolidated Omnibus Budget Reconciliation Act for a maximum of 12 months ("COBRA Premium Reimbursement"). Dr. Davidson will receive only the Accrued Obligations and not be eligible for further compensation if his employment ends for reasons other than termination by the Company without Cause or termination by him for Good Reason.

In the event Dr. Davidson's employment is terminated by the Company without Cause or by Dr. Davidson for Good Reason (if termination is requested by a third party) within three months prior to a Change-in-Control (as defined in the Davidson Agreement) or during the 12 months following such Change-in-Control, Dr. Davidson will be entitled to receive the severance payments and benefits described above. In addition, all of Dr. Davidson's time-based stock options and equity awards will accelerate, becoming fully exercisable and nonforfeitable as of the termination date and the exercise period for certain vested options will be extended.

Dr. Davidson is entitled to a base salary and annual performance bonus in cash targeted at 50% of his base salary, at our discretion and subject to Dr. Davidson's continued employment through the payment date of such bonus. Dr. Davidson is eligible to participate in our equity incentive plans, including the Company's LTIP, and other employee benefits and insurance programs generally made available to our full-time U.S.-based executives. Dr. Davidson is also party to a Confidentiality and Assignment of Inventions Agreement, which includes certain customary non-competition, non-solicitation, confidentiality and assignment of inventions obligations in favor of the Company.

Employment Agreement with Ian Somaiya

We entered into an employment agreement with Mr. Somaiya, our Chief Financial Officer, dated October 6, 2023 (the "Somaiya Agreement"). Pursuant to the Somaiya Agreement, in the event Mr. Somaiya's employment is terminated by the Company without Cause (as defined in the Somaiya Agreement) or by him for Good Reason (as defined in the Somaiya Agreement), we would be required, subject to customary conditions, to pay Mr. Somaiya, in addition to certain Accrued Obligations (as defined in the Somaiya Agreement), an amount equal to 12 months of his base salary, any bonus earned or payable and a prorated bonus for the calendar year in which the termination occurred, and COBRA Premium Reimbursement. Mr. Somaiya will receive only the Accrued Obligations and not be eligible for further compensation if his employment ends for reasons other than termination by the Company without Cause or termination by him for Good Reason.

In the event Mr. Somaiya's employment is terminated by the Company without Cause or by Mr. Somaiya for Good Reason (if termination is requested by a third party) within three months prior to a Change-in-Control (as defined in the Somaiya Agreement) or during the 12 months following such Change-in-Control, Mr. Somaiya will be entitled to receive the severance payments and benefits described above. In addition, all of Mr. Somaiya's time-based stock options and equity awards will accelerate, becoming fully exercisable and nonforfeitable as of the termination date and the exercise period for certain vested options will be extended.

Mr. Somaiya is entitled to a base salary and annual performance bonus in cash targeted at 45% of his base salary, at our discretion and subject to Mr. Somaiya's continued employment through the payment date of such bonus. Mr. Somaiya is eligible to participate in our equity incentive plans, including the Company's LTIP, and other employee benefits and insurance programs generally made available to our full-time U.S.-based executives. Mr. Somaiya is also party to a Confidentiality and Assignment of Inventions Agreement, which includes certain customary non-competition, non-solicitation, confidentiality and assignment of inventions obligations in favor of the Company.

Employment Agreement with John Kastelein, M.D., Ph.D FESC

We entered into an employment agreement with Dr. Kastelein, our Chief Scientific Officer, dated November 18, 2022 (the "Kastelein Agreement"). Pursuant to the Kastelein Agreement, in the event Dr. Kastelein's employment is terminated by the Company without Cause (as defined in the Kastelein Agreement), we would be required, subject to customary conditions, to pay Dr. Kastelein an amount equal to 12 months of his base salary.

Dr. Kastelein is entitled to a base salary and annual performance bonus in cash targeted at 40% of his base salary, at our discretion and subject to Dr. Kastelein's continued employment through the payment date of such bonus. Dr. Kastelein is eligible to participate in our equity incentive plans, including the LTIP, and other employee benefits and insurance programs offered by us. Dr. Kastelein is also party to a Confidentiality and Assignment of Inventions Agreement, which includes certain customary non-competition, non-solicitation, confidentiality and assignment of inventions obligations in favor of the Company.

Employment Agreement with Douglas Kling

We entered into an employment agreement with Mr. Kling, our Chief Operating Officer, dated January 24, 2023 (the "Kling Agreement"). Pursuant to the Kling Agreement, in the event Mr. Kling's employment is terminated by the Company without Cause (as defined in the Kling Agreement) or by him for Good Reason (as defined in the Kling Agreement), we would be required, subject to customary conditions, to pay Mr. Kling, in addition to certain Accrued Obligations (as defined in the Kling Agreement), an amount equal to 12 months of his base salary, any bonus earned or payable and a prorated bonus for the calendar year in which the termination occurred, and COBRA Premium Reimbursement. Mr. Kling will receive only the Accrued Obligations and not be eligible for further compensation if his employment ends for reasons other than termination by the Company without Cause or termination by him for Good Reason.

In the event Mr. Kling's employment is terminated by the Company without Cause or by Mr. Kling for Good Reason (if termination is requested by a third party) within three months prior to a Change-in-Control (as defined in the Somaiya Agreement) or during the 12 months following such Change-in-Control, Mr. Kling will be entitled to receive the severance payments and benefits described above. In addition, all of Mr. Kling's time-based stock options and equity awards will accelerate, becoming fully exercisable and nonforfeitable as of the termination date and the exercise period for certain vested options will be extended.

Mr. Kling is entitled to a base salary and annual performance bonus in cash targeted at 40% of his base salary, at our discretion and subject to Mr. Kling's continued employment through the payment date of such bonus. Mr. Kling is eligible to participate in our equity incentive plans, including the Company's LTIP, and other employee benefits and insurance programs generally made available to our full-time U.S.-based executives. Mr. Kling is also party to a Confidentiality and Assignment of Inventions Agreement, which includes certain customary non-competition, non-solicitation, confidentiality and assignment of inventions obligations in favor of the Company.

Employment Agreement with Juliette Audet

In connection with Ms. Audet's employment with the Company as our Chief Business Officer, Ms. Audet entered into an employment agreement with Globalization Partners Switzerland SA, a labor leasing company, in her country of residence, dated March 21, 2024, which sets forth terms relating to her employment with us (the "Audet Employment Agreement"). Pursuant to the Audet Employment Agreement, Ms. Audet is entitled to a base salary and an annual bonus and is eligible to participate in our equity incentive plans, including the LTIP, and other employee benefits and insurance programs offered by us.

The Company also entered into a separate letter agreement with Ms. Audet that has additional provisions with respect to her eligibility for certain severance benefits (the "Audet Letter Agreement"). Under the Audet Letter Agreement, if Ms. Audet's employment is terminated by us without Cause or by her for Good Reason (each as defined in the Audet Letter Agreement), we would be obligated to pay her a severance amount equal to 12 months of her base salary, any bonus earned or payable and a pro rata bonus for the calendar year in which the termination occurred. If Ms. Audet's employment is terminated by us without Cause or by her for Good Reason (if termination is requested by a third party) within three months prior to a Change-in-Control (as defined in the Audet Letter Agreement) or during the 12 months following such Change-in-Control, she will be entitled to receive the severance payments and benefits described above. In addition, all of Ms. Audet's time-based stock options and equity awards will accelerate, becoming fully exercisable and nonforfeitable as of the termination date, and the exercise period for certain vested options will be extended.

The table below provides the potential payments and benefits to which our NEOs would be entitled, assuming their employment was terminated as of December 31, 2024, including in connection with a change in control, based on the termination benefits in effect as of December 31, 2024.

Name and Principal Position		Compensation Component	Involuntary or Good Reason Termination without a Change-in-Control ($)	Involuntary or Good Reason Termination in Connection with a Change-in-Control ($)
Michael Davidson, M.D.	(1)	Cash Severance	931,950	931,950
		Long-term Incentives	—	41,344,023
		Benefits and Perquisites	23,871	23,871
		Total:	955,821	42,299,844
Ian Somaiya	(1)	Cash Severance	678,600	678,600
		Long-term Incentives	—	10,766,007
		Benefits and Perquisites	35,711	35,711
		Total:	714,311	11,480,318
John Kastelein, M.D., Ph.D. FESC	(2)	Cash Severance	486,046	486,046
		Long-term Incentives	—	—
		Benefits and Perquisites	—	—
		Total:	486,046	486,046
Juliette Audet	(3)	Cash Severance	601,541	601,541
		Long-term Incentives	—	1,082,500
		Benefits and Perquisites	—	—
		Total:	601,541	1,684,041
Douglas Kling	(1)	Cash Severance	700,000	700,000
		Long-term Incentives	—	12,385,275
		Benefits and Perquisites	35,711	35,711
		Total:	735,711	13,120,986

(1)Under the employment agreements between us and Dr. Davidson, Mr. Somaiya and Mr. Kling, respectively, if their employment is terminated by us without Cause or by them for Good Reason, we would be obligated to pay them an severance amount equal to 12 months of their base salary, any bonus earned or payable and a prorated bonus for the calendar year in which the termination occurred, and premium reimbursement equal to the monthly employer contribution that we would have made to provide health coverage under the Consolidated Omnibus Budget Reconciliation Act for a maximum of 12 months. If their employment is terminated by us without Cause or by them for Good Reason (if termination is requested by a third party) within three months prior to a Change-in-Control or during the 12 months following such Change-in-Control, they will be entitled to receive the severance payments and benefits described above. In addition, all of their time-based stock options and equity awards will accelerate, becoming fully exercisable and nonforfeitable as of the termination date and the exercise period for certain vested options will be extended.

(2)Under the employment agreement between us and Dr. Kastelein, if his employment is terminated by us without Cause, we would be obligated to pay him a severance amount equal to 12 months of his base salary.

(3)Under the Audet Letter Agreement, if Ms. Audet's employment is terminated by us without Cause or by her for Good Reason, we would be obligated to pay her a severance amount equal to 12 months of her base salary, any bonus earned or payable and a pro rata bonus for the calendar year in which the termination occurred. If Ms. Audet's employment is terminated by us without Cause or by her for Good Reason (if termination is requested by a third party) within three months prior to a Change-in-Control or during the 12 months following such Change-in-Control, she will be entitled to receive the severance payments and benefits described above. In addition, all of Ms. Audet's time-based stock options and equity awards will accelerate, becoming fully exercisable and nonforfeitable as of the termination date and the exercise period for certain vested options will be extended.

Equity Incentive Plans

LTIP

We have established our LTIP, under which we may grant options, restricted shares, restricted share units, share appreciation rights and other equity and equity-based awards. As of December 31, 2024, the total number of Ordinary Shares underlying awards granted under the LTIP (other than awards granted as Earnout RSUs in accordance with the Business Combination Agreements or as replacement awards in connection with a merger or business combination) will not exceed 17,772,578; provided that the number of Ordinary Shares reserved for grant under the LTIP 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.

The LTIP is administered by the Board of Directors and the Compensation Committee. The Board of Directors has delegated authority to grant awards under the LTIP to the Compensation Committee for awards to eligible participants not then serving on the Compensation Committee. The Board of Directors has also delegated the authority to grant awards under the LTIP to non-executive officers to Dr. Davidson who will determine when to grant equity awards and the terms of such awards. We may grant awards under the LTIP to our directors, employees, consultants or other advisors. The Board of Directors or the Compensation Committee may condition awards under the LTIP upon the achievement or satisfaction of performance criteria and/or continued service with the Company and determines the vesting conditions for awards under the LTIP. The LTIP includes provisions for good leavers and bad leavers as well as for change-in-control.

Rollover Option Plan

We also established a rollover option plan (the “Rollover Plan”) in connection with the closing of the Business Combination, under which we assumed the outstanding options of certain optionholders of NewAmsterdam Pharma Holding B.V. who held their options through entities

in exchange for a grant of options to acquire Ordinary Shares. The total number of Ordinary Shares underlying the options covered by the Rollover Plan is 1,736,545. Any Ordinary Shares underlying options granted under the Rollover Plan that are forfeited, canceled or otherwise terminated will become available for issuance under the LTIP.

The Rollover Plan is administered by the Board of Directors and the Compensation Committee. The Rollover Plan includes provisions applicable in the event of a change-in-control.

Supplementary LTIP

We have also established our supplementary long-term incentive plan (the "Supplementary LTIP"), under which we may grant options, restricted shares, restricted share units, share appreciation rights and other equity and equity-based awards to our employees and consultants (but not our directors). The total number of Ordinary Shares underlying awards that may be granted under the Supplementary LTIP (other than awards granted as replacement awards in connection with a merger or business combination) will not exceed 1,040,233.

The Supplementary LTIP is administered by the Board of Directors and the Compensation Committee. The Board of Directors has delegated authority to grant awards under the Supplementary LTIP to the Compensation Committee for awards to anyone not then serving on the Compensation Committee. The Board of Directors has also delegated the authority to grant awards under the Supplementary LTIP to non-executive officers to Dr. Davidson, who will determine when to grant equity awards and the terms of such awards. The awards issued under the Supplementary LTIP will have terms substantially similar to those issued under the LTIP. The Supplementary LTIP includes provisions applicable in the event of a change-in-control.

Inducement Plan

We have also established our inducement plan (the "Inducement Plan"), under which we may grant options, restricted shares, restricted share units, share appreciation rights and other equity-based awards to our newly-hired (or newly-hired, after a bona fide period of non-employment) employees (but not directors). The total number of Ordinary Shares underlying awards that may be granted under the Inducement Plan will not exceed 1,500,000.

The Inducement Plan is administered exclusively by the Compensation Committee. The Inducement Plan includes provisions applicable in the event of a change-in-control.

Limitation of Liability and Indemnification

Under Dutch law, our directors may be held liable for damages in the event of improper or negligent performance of their duties. They may be held liable for damages to the Company and to third parties for infringement of the Articles of Association or of certain provisions of Dutch law. In certain circumstances, they may also incur other specific civil, administrative and criminal liabilities. Subject to certain exceptions, the Articles of Association provide for indemnification of our current and former directors and other current and former officers and employees as designated by the Board of Directors. No indemnification under the Articles of Association will be given to an indemnified person:

- if a competent court or arbitral tribunal has established, without having (or no longer having) the possibility for appeal, that the acts or omissions of such indemnified person that led to the financial losses, damages, expenses, suit, claim, action or legal proceedings as described above are of an unlawful nature (including acts or omissions which are considered to constitute malice, gross negligence, intentional recklessness and/or serious culpability attributable to such indemnified person);
- to the extent that his or her financial losses, damages and expenses are covered under insurance and the relevant insurer has settled, or has provided reimbursement for, these financial losses, damages and expenses (or has irrevocably undertaken to do so);
- in relation to proceedings brought by such indemnified person against us, except for proceedings brought to enforce indemnification to which he or she is entitled pursuant to the Articles of Association, pursuant to an agreement between such indemnified person and us, which has been approved by us or pursuant to insurance taken out by us for the benefit of such indemnified person; and
- for any financial losses, damages or expenses incurred in connection with a settlement of any proceedings effected without our prior consent.

Under the Articles of Association, the Board of Directors may stipulate additional terms, conditions and restrictions in relation to the indemnification described above.

We have also entered into indemnification agreements with each of our directors and executive officers providing for procedures for indemnification and advancements by us of certain expenses and costs relating to claims, suits or proceedings arising from his or her service to us or, at our request, service to other entities, as officers or directors to the maximum extent permitted by Dutch law and subject to the exceptions provided in such agreements.

Compensation Committee Interlocks and Insider Participation

The Compensation Committee consists of Louis Lange, M.D., Ph.D., William H. Lewis and Mark C. McKenna. All members of the compensation committee are independent directors, and none of our executive officers or former executive officers served on the compensation committee or on the board of any company that employed any member of the compensation committee or the Board of Directors during the year ended December 31, 2024.

Director Compensation

Director Compensation

The Board of Directors and the Compensation Committee determine the compensation of individual directors in accordance with our compensation policy to the extent applicable. All non-employee directors are paid an annual retainer of $43,000. Non-employee directors may receive further compensation ranging from $5,000 to $20,000 for serving as chair or member of committees (i.e., Audit Committee or Compensation Committee). We have also granted and expect to continue granting certain non-employee directors, other than those affiliated with our significant shareholders, options to purchase Ordinary Shares as compensation for their service on the Board of Directors.

Director Service Agreement

We entered into services agreements with all of our directors which regulate their services as our directors. These services agreements, except for James N. Topper's services agreement, contain non-competition and non-solicitation arrangements, as well as a requirement to assign and transfer to us any intellectual and industrial property rights originating from the director's services as a director or inventor for us, but do not provide for compensation.

Director Indemnification Agreements

The Articles of Association require us to indemnify our current and former directors to the fullest extent permitted by law, subject to certain exceptions. We entered into indemnification agreements with all of our directors providing for procedures for indemnification and advancements by us of certain expenses and costs relating to claims, suits or proceedings arising from their service to us or, at our request, service to other entities, as directors or officers to the maximum extent permitted by law.

Director Compensation Table

The following table sets forth information regarding the compensation earned for service on the Board of Directors by our non-employee directors during the year ended December 31, 2024. We reimburse members of the Board of Directors for reasonable travel and out-of-pocket expenses incurred in connection with attending Board of Directors and committee meetings.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Non-Employee Directors				
William H. Lewis, J.D., M.B.A.	105,500	555,345	—	660,845
Mark C. McKenna (2)	26,250	661,252	—	687,502
Juliette Audet (2)	10,000	—	—	10,000
Nicholas Downing, M.D.	44,000	—	—	44,000
Wouter Joustra (2)	20,000	—	—	20,000
Louis Lange, M.D., Ph.D.	57,750	51,417	—	109,167
Sander Slootweg (2)	20,000	—	—	20,000
John W. Smither	57,500	51,417	—	108,917
James N. Topper, M.D., Ph.D.	40,000	—	—	40,000
Janneke van der Kamp	46,375	51,417	—	97,792

(1) The amounts reported in these columns reflect the aggregate grant date fair value of the stock options granted to our directors as computed in accordance with ASC 718. See Note 8 to the Consolidated Financial Statements in this Annual Report for a discussion of assumptions made by us in determining the aggregate grant date fair value of our option awards and stock awards. Note that the amounts reported in these columns do not reflect the actual economic value that may be realized by the directors.

(2) 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.

The following table provides information regarding the aggregate number of shares underlying option awards granted to our non-employee directors that were outstanding as of December 31, 2024:

Name	Option Awards (#)
William H. Lewis, J.D., M.B.A.	100,000
Mark C. McKenna	72,500
Louis Lange, M.D., Ph.D.	237,769
John W. Smither	28,600
Janneke van der Kamp	28,000

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Securities Authorized For Issuance Under Equity Compensation Plans

Our LTIP and Rollover Plan are our only equity compensation plans approved by our shareholders. The Supplementary LTIP and the Inducement Plan were approved by the Board of Directors but were not approved by our shareholders. The following table sets forth certain information as of December 31, 2024 with respect to our LTIP, Rollover Plan, Supplementary LTIP and Inducement Plan:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options (A)		Weighted-Average Exercise Price of Outstanding Options (B)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (A)) (C)
Equity compensation plans approved by shareholders:	17,308,526	$	9.46	315,414
LTIP [1]	16,070,224	$	10.10	315,414
Rollover Plan	1,238,302	$	1.2092 [3]	-
Equity compensation plans not approved by shareholders:	1,720,530		15.84	789,419
Supplementary LTIP [2]	958,730	$	13.63	51,219
Inducement Plan	761,800	$	18.62	738,200
Total:	19,029,056	$	10.04	1,104,833

(1)The number of Ordinary Shares reserved for grant under the LTIP 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.

(2)See the section titled "*Executive Compensation—Equity Incentive Plans*" and Note 10 to the Consolidated Financial Statements included in this Annual Report for a brief description of the terms of the Supplementary LTIP.

(3)The exercise price of the options included in the Rollover Plan is Euro 1.16392 and has been converted into USD in the table above at a rate of $1.0389 per Euro, which was the exchange rate as of December 31, 2024 as published by European Central Bank.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information regarding the actual beneficial ownership of Ordinary Shares as of February 18, 2025, by:

- each person, or group of affiliated persons, known by the Company to beneficially own more than 5% of outstanding Ordinary Shares;
- each of our executive officers or directors; and
- all of our executive officers and directors, as a group.

The SEC has defined "beneficial ownership" of a security to mean the possession, directly or indirectly, of voting power and/or investment power over such security. A shareholder is also deemed to be, as of any date, the beneficial owner of all securities that such shareholder has the right to acquire within 60 days after that date through (i) the exercise of any option, warrant or right, (ii) the conversion of a security, (iii) the power to revoke a trust, discretionary account or similar arrangement, or (iv) the automatic termination of a trust, discretionary account or similar arrangement. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, Ordinary Shares subject to options or other rights (as set forth above) held by that person that are currently exercisable, or will become exercisable within 60 days thereafter, are deemed outstanding, while such shares are not deemed outstanding for purposes of computing percentage ownership of any other person. Each person named in the table has sole voting and investment power with respect to all of the Ordinary Shares shown as beneficially owned by such person, except as otherwise indicated in the table or footnotes below.

The beneficial ownership of Ordinary Shares is based on 109,817,812 Ordinary Shares issued and outstanding, as of February 18, 2025. Unless otherwise indicated, we believe that all persons named in the table below have sole voting and investment power with respect to all Ordinary Shares beneficially owned by them. To our knowledge, no Ordinary Shares beneficially owned by any executive officer, director or director nominee have been pledged as security. None of our shareholders has different voting rights from other shareholders.

Name of Beneficial Owner	Number of Shares Beneficially Owned Shares	Percentage of Ordinary Shares Beneficially Owned (%) %
Named Executive Officers, Directors and Director Nominees		
Michael Davidson, M.D. [1]	4,216,060	3.72%
Ian Somaiya [2]	272,385	*
John Kastelein, M.D., Ph.D. FESC [3]	1,961,852	1.76%
Douglas Kling [4]	782,515	*
Juliette Audet [5]	1,104	*
Nicholas Downing, M.D. [6]	—	—
Louis Lange, M.D., Ph.D. [7]	235,699	*
William H. Lewis, J.D., M.B.A. [8]	31,252	*
John W. Smither [9]	13,597	*
James N. Topper, M.D., Ph.D. [10]	16,416,751	14.88%
Janneke van der Kamp [11]	12,127	*
Mark McKenna	—	—
Wouter Joustra [12]	—	—
All executive officers and directors as a group (15 persons)	24,943,411	21.14%

Name of Beneficial Owner	Number of Shares Beneficially Owned Shares	Percentage of Ordinary Shares Beneficially Owned (%) %
Other 5% Shareholders		
Entities affiliated with Forbion [13]	10,656,172	9.70%
Frazier Lifesciences Sponsor LLC and affiliates [14]	16,416,751	14.88%
Entities affiliated with Bain Capital Life Sciences Investors, LLC [15]	11,143,891	9.99%
RA Capital Healthcare Fund, L.P. [16]	8,397,333	7.62%
Viking Global Investors LP [17]	8,024,565	7.31%

* Indicates beneficial ownership of less than 1% of total outstanding Ordinary Shares.

(1)Consists of (i) 209,784 Ordinary Shares, (ii) options to purchase 3,312,497 Ordinary Shares, exercisable within 60 days of February 18, 2025, (iii) Warrants to purchase 85,000 Ordinary Shares, exercisable within 60 days of February 16, 2024 and (iv) 608,779 Ordinary Shares subject to forfeiture underlying depositary receipts issued by Stichting Administratiekantoor EPNAP ("STAK EPNAP"). STAK EPNAP has sole voting and investment power over the securities described in (iv) while underlying the depositary receipts and are presented here because the depositary receipts can be cancelled by the board of directors of STAK EPNAP at any time as a consequence of which the shareholder will become the beneficial owner of the securities underlying the depositary receipts.

(2)Consists of options to purchase 272,385 Ordinary Shares, exercisable within 60 days of February 18, 2025.

(3)Consists of (i) options to purchase 970,229 Ordinary Shares held by Futurum B.V. through PoolCo and (ii) options to purchase 991,623 Ordinary Shares held by Dr. Kastelein directly, each exercisable within 60 days of February 18, 2025.

(4)Consists of options to purchase 782,515 Ordinary Shares, exercisable within 60 days of February 18, 2025.

(5)Consists of 1,104 Ordinary Shares.

(6)Does not include Ordinary Shares held by the Bain Capital Life Sciences Entities (as defined below). Dr. Downing serves as a Managing Director of Bain Capital Life Sciences Investors, LLC.

(7)Consists of (i) 24,878 Ordinary Shares (ii) Warrants to purchase 44,619 Ordinary Shares, exercisable within 60 days of February 18, 2025 and (iii) options to purchase 166,202 Ordinary Shares, exercisable within 60 days of February 18, 2025.

(8)Consists of options to purchase 31,252 Ordinary Shares, exercisable within 60 days of February 18, 2025.

(9)Consists of options to purchase 13,597 Ordinary Shares, exercisable within 60 days of February 18, 2025.

(10)Consists of the shares described in Note 14. Dr. Topper disclaims beneficial ownership of the shares referenced in Note 14, except to the extent of his pecuniary interest therein, if any.

(11)Consists of options to purchase 12,127 Ordinary Shares, exercisable within 60 days of February 18, 2025.

(12)See Note 13. Mr. Joustra is a member of the Board of Directors and is a partner of Forbion Growth Management B.V. ("Growth Management") and a member of the investment committee of Growth Management, but does not have beneficial ownership of the securities referenced in Note 13.

(13)Consists of (i) 5,976,287 Ordinary Shares beneficially owned by Forbion Capital Fund IV Coöperatief U.A. ("Forbion IV") through ForGrowth NAP B.V. ("ForGrowth") that are held directly by NAP PoolCo B.V. ("PoolCo"), (ii) 4,027,712 Ordinary Shares beneficially owned by Forbion Growth Opportunities Fund I Coöperatief U.A. ("Forbion Growth") through ForGrowth that are held directly by PoolCo and (iii) 652,173 Ordinary Shares held directly by ForGrowth. ForGrowth is a joint-investment vehicle wholly owned by Forbion IV and Forbion Growth. PoolCo is a Dutch limited liability company that holds Ordinary Shares on behalf of its shareholders. The governing documents of PoolCo vest voting and investment control over the Ordinary Shares held by PoolCo in PoolCo's shareholders and, as a result, PoolCo disclaims beneficial ownership of such Ordinary Shares. The information herein is based solely on the Form 4 filed by the holders on January 2, 2025. The address for the Forbion entities is Gooimeer 2-35, 1411 DC Naarden, the Netherlands.

Forbion IV Management B.V. ("Forbion IV Management") may be deemed to have voting and dispositive power over the Ordinary Shares beneficially owned by Forbion IV. Investment decisions with respect to the Ordinary Shares held by Forbion IV are made by its investment committee which may delegate such powers to the authorized representatives of Forbion IV Management. Mssrs. Slootweg, van Osch, Mulder, van Houten, van Deventer, Reithinger, Kersten and Boorsma are partners of Forbion IV Management, which is the director of and acts as the investment advisor to Forbion IV.

Growth Management may be deemed to have voting and dispositive power over the Ordinary Shares beneficially owned by Forbion Growth. Investment decisions with respect to the Ordinary Shares held by Forbion Growth are made by its investment committee which may delegate such powers to the authorized representatives of Growth Management. Mssrs. Slootweg, van Osch, Mulder, van Houten, van Deventer, Reithinger, Kersten, Joustra, Bos en Lüneborg and Boorsma are partners of Growth Management, which is the director of and acts as the investment advisor to Forbion Growth.

(14)Consists of 3,801,000 Ordinary Shares and Warrants to purchase 167,000 Ordinary Shares held by Frazier Lifesciences Sponsor LLC (the "Sponsor"). The sole member of the Sponsor is Frazier Life Sciences X, L.P. ("FLS X"). FHMLS X, L.P. is the general partner of FLS X and FHMLS X, L.L.C. is the general partner of FHMLS X, L.P. Patrick J. Heron and James N. Topper are the members of FHMLS X, L.L.C. and managers of each of FLS X, FHMLS X, L.P. and FHMLS X, L.L.C.

Also included in the total number are (i) 3,008,429 Ordinary Shares and Warrants to purchase 333,333 Ordinary Shares held by FLS X, (ii) 1,131,077 Ordinary Shares held by Frazier Life Sciences XI, L.P. ("FLS XI"), (iii) 5,134,071 Ordinary Shares held by Frazier Life Sciences Public Fund, L.P. ("FLSPF") and (iv) 2,841,841 Ordinary Shares held by Frazier Life Sciences Overage Fund, L.P. ("FLSOF"). FHMLS XI, L.P. is the general partner of FLS XI and FHMLS XI, L.L.C. is the general partner of FHMLS XI, L.P. Patrick J. Heron, Dan Estes and James N. Topper are the members of FHMLS XI, L.L.C. and managers of each of FLS XI, FHMLS XI, L.P. and FHMLS XI, L.L.C. FHMLSP, L.P. is the general partner of FLSPF and FHMLSP, L.L.C. is the general partner of FHMLSP, L.P. Patrick J. Heron, James N. Topper, Albert Cha and James Brush are the members of FHMLSP, L.L.C. and managers of each of FLSPF, FHMLSP, L.P. and FHMLSP, L.L.C. FHMLSP Overage, L.P., is the general partner of FLSOF and FHMLSP Overage, L.L.C. is the general partner of FHMLSP Overage, L.P. Patrick J. Heron, James N. Topper, Albert Cha and James Brush are the members of FHMLSP Overage, L.L.C. and managers of each of FLSOF, FHMLSP Overage, L.P. and FHMLSP Overage, L.L.C. The information herein is based on the Schedule 13D/A filed by Sponsor, FLS X, FLS XI, FLSPF, FLSOF, FHMLS X, L.P., FHMLS X, L.L.C., FHMLS XI, L.P., FHMLS XI, L.L.C., FHMLSP, L.P., FHMLSP, L.L.C., FHMLSP Overage, L.P., FHMLSP Overage, L.L.C., Mr. Cha, Mr. Brush, Mr. Heron, Mr. Estes and Mr. James Topper on December 17, 2024. The address of these holders is Two Union Square, 601 Union St., Suite 3200, Seattle, WA 98101.

(15)Consists of (i) 4,797,557 Ordinary Shares held by BCLS II Investco, LP ("BCLS II Investco"), (ii) 5,376,356 Ordinary Shares held by BCLS Fund III Investments, LP ("BCLS Fund III"), (iii) 267,429 Ordinary Shares and Warrants to purchase 89,143 Ordinary Shares held by Bain Capital Life Sciences Fund II, L.P. ("BCLS Fund II"), (iv) 32,571 Ordinary Shares and Warrants to purchase 10,857 Ordinary Shares held by BCIP Life Sciences Associates, LP ("BCIPLS") and (v) 1,257,141 Ordinary Shares issuable upon exercise of a pre-funded warrant (the "Pre-Funded Warrant") held by Bain Capital Life Sciences Opportunities III GP, LLC ("BCLS Fund III Opportunities") and 375,512 Ordinary Shares issuable upon exercise of a Pre-Funded Warrant held by BCLS II Equity Opportunities, LP ("BCLS Fund II Opportunities," and, together with BCIPLS, BCLS II Investco, BCLS Fund III and BCLS Fund II, the "Bain Capital Life Sciences Entities"), which are currently exercisable, except to the extent such exercise is restricted by a blocker provision which restricts the exercise of such warrant if, as a result of such exercise, the holder, together with its affiliates and any other persons whose beneficial ownership would be aggregated with the holder for purposes of Section 13(d) of the Exchange Act, would beneficially own more than 9.99% of the total number of Ordinary Shares then outstanding immediately following such exercise (the "Warrant Beneficial Ownership Limitation"). Excludes 1,062,675 Ordinary Shares issuable upon exercise of a Pre-Funded Warrant held by BCLS Fund III Opportunities

and BCLS Fund II Opportunities, which is currently exercisable, but such shares have been excluded because the exercise thereof is restricted by the Warrant Beneficial Ownership Limitation. Bain Capital Life Sciences Investors, LLC ("BCLSI") (a) is the manager of Bain Capital Life Sciences Investors II, LLC, which is the general partner of BCLS Fund II, which is the managing member of BCLS II Investco (GP), LLC, which is the general partner of BCLS II Investco, (b) is the manager of Bain Capital Life Sciences III General Partner, LLC, which is the general partner of Bain Capital Life Sciences Fund III, L.P., which is the managing member of BCLS Fund III Investments GP, LLC, which is the general partner of BCLS Fund III, and (c) governs the investment strategy and decision-making process with respect to investments held by BCIPLS. As a result, BCLSI may be deemed to share voting and dispositive power with respect to the securities held by the Bain Capital Life Sciences Entities. The address of the Bain Capital Life Sciences entities is c/o Bain Capital Life Sciences, LP, 200 Clarendon Street, Boston, MA 02116. The information herein is based solely on the Schedule 13D/A filed by certain of Bain Capital Life Sciences Entities on December 17, 2024 and the Form 4 filed by certain of Bain Capital Life Sciences Entities on December 17, 2024.

(16)Consists of 8,064,000 Ordinary Shares and Warrants to purchase 333,333 Ordinary Shares held by RA Capital Healthcare Fund, L.P. ("RACHF"). RA Capital Management, L.P. ("RA Capital") is the investment manager for RACHF. The general partner of RA Capital is RA Capital Management GP, LLC, of which Peter Kolchinsky and Rajeev Shah are the managing members. Each of Mr. Kolchinsky and Mr. Shah may be deemed to have voting and investment power over the Ordinary Shares held by RACHF. Mr. Kolchinsky and Mr. Shah disclaim beneficial ownership of such shares, except to the extent of any pecuniary interest therein. RA Capital serves as investment adviser for RACHF and may be deemed a beneficial owner of the securities described herein as held by RACHF. RACHF has delegated to RA Capital the sole power to vote and the sole power to dispose of all securities held in RACHF's portfolios, including the Ordinary Shares reported herein. Because RACHF has divested itself of voting and investment power over the reported securities they hold and may not revoke that delegation on less than 61 days' notice, RACHF disclaims beneficial ownership of the securities they hold. The business address of the persons and entities set forth herein is 200 Berkeley Street, 18th Floor, Boston, MA 02116. The information herein is based solely on the Schedule 13G/A filed by RACHF, RA Capital, Mr. Kolchinsky and Mr. Shah on November 14, 2024.

(17)Consists of 5,376,459 Ordinary Shares and 2,648,106 Ordinary Shares owned by Viking Global Opportunities Illiquid Investments Sub-Master LP ("VGOP") and Viking Global Opportunities Drawdown (Aggregator) LP ("VGOD"), respectively. Viking Global Investors LP ("VGI") provides managerial services to VGOP and VGOD and has the authority to dispose of and vote the Ordinary Shares that VGOP and VGOD directly own to and as a result may be deemed to beneficially own the Ordinary Shares that VGOP and VGOD directly. Viking Global Opportunities Parent GP LLC ("Opportunities Parent") is the sole member of Viking Global Opportunities GP LLC ("Opportunities GP"), which has the authority to dispose of and vote the Ordinary Shares controlled by Viking Global Opportunities Portfolio GP LLC ("Opportunities Portfolio GP") (which consists of the Ordinary Shares that VGOP directly owns) and is the sole member of Viking Global Opportunities Drawdown GP LLC ("VGOD GP"), which has the authority to dispose of and vote the Ordinary Shares controlled by Viking Global Opportunities Drawdown Portfolio GP LLC ("VGOD Portfolio GP") (which consists of the Ordinary Shares that VGOD directly owns). Opportunities Parent does not directly own any Ordinary Shares. Opportunities GP serves as the sole member of Opportunities Portfolio GP and has the authority to dispose of and vote the Ordinary Shares controlled by Opportunities Portfolio GP. Opportunities Portfolio GP serves as the general partner of VGOP and has the authority to dispose of and vote the Ordinary Shares that VGOP directly owns. VGOD GP serves as the sole member of VGOD Portfolio GP and has the authority to dispose of and vote the Ordinary Shares controlled by VGOD Portfolio GP. VGOD Portfolio GP serves as the general partner of VGOD and has the authority to dispose of and vote the Ordinary Shares that VGOD directly owns. O. Andreas Halvorsen, David C. Ott and Rose S. Shabet, as Executive Committee Members of Viking Global Partners LLC (general partner of VGI) and Opportunities Parent, have shared authority to dispose of and vote the Ordinary Shares beneficially owned by VGI and Opportunities Parent. None of Mr. Halvorsen, Mr. Ott and Ms. Shabet directly owns any Ordinary Shares. Each of Mr. Halvorsen, Mr. Ott and Ms. Shabet may be deemed to beneficially own the Ordinary Shares that VGOP and VGOD directly own. The business address of the persons and entities set forth herein is 55 Railroad Avenue, Greenwich, Connecticut 06830. The information herein is based solely on the Schedule 13G/A filed by VGI, Opportunities Parent, Opportunities GP, Opportunities Portfolio GP, VGOP, VGOD GP, VGOD Portfolio GP, VGOD, Mr. Halvorsen, Mr. Ott and Ms. Shabet on February 14, 2024.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Independence of the Board of Directors

The nomination and corporate governance committee and Board of Directors have undertaken a review of the independence of our directors and considered whether any director has a relationship that, in the opinion of such committee or the Board of Directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a member of the Board of Directors. Based upon information requested from and provided by each director concerning such director's background, employment and affiliations, including family relationships, the Board of Directors has determined that all of our directors, other than Dr. Davidson and Dr. Kastelein, are "independent directors," as such term is defined in Nasdaq Rule 5605(a)(2). In making these determinations, the Board of Directors considered the current and prior relationships that each director has with the Company and all other facts and circumstances that the Board of Directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each director.

Certain Relationships and Related Transactions

Review, Approval or Ratification of Transactions with Related Persons

We adopted a related party transaction policy that requires the review and, if applicable, approval or ratification of any related party transaction by the Board of Directors, the Audit Committee or another designated committee consisting solely of independent directors. Our Audit Committee will review this related party transaction policy periodically and will recommend changes to the Board of Directors as appropriate.

In addition, under Dutch law and the Articles of Association, our directors may not take part in any discussion or decision-making that involves a subject or transaction in relation to which he or she has a direct or indirect personal conflict of interest with us. Such a conflict of interest would generally arise if the director concerned is unable to serve our interests and the business connected with us with the required level of integrity and objectivity due to the existence of the conflicting personal interest. The Articles of Association provide that if as a result of conflicts of interests no resolution of the Board of Directors can be adopted, the resolution may nonetheless be adopted by the Board of Directors as if none of our directors had a conflict of interest. In that latter case, each of our director is entitled to participate in the discussion and decision-making process and to cast a vote.

A related party transaction is generally any transaction in which the Company or its subsidiaries is or will be a participant, in which the amount involved exceeds $120,000, and a director (or nominee), executive officer, immediate family member, or any beneficial owner of more than 5% of our Ordinary Shares, has or will have a direct or indirect material interest.

Certain Related Party Transactions

Investor Rights Agreement

In connection with the closing of the Business Combination, we entered into the Investor Rights Agreement, dated November 22, 2022 (the "Investor Rights Agreement"), with the Sponsor and the former FLAC directors (the "FLAC Initial Shareholders"), and certain NewAmsterdam Pharma shareholders agreed not to sell, assign, offer to sell, contract, pledge, grant, or otherwise dispose of or enter into any swap or other similar arrangement, with respect to the Ordinary Shares such persons received in connection with the Business Combination for six months from the date the Domestication became effective (the "Final Closing Date"), subject to certain limited exceptions. In addition, the FLAC Initial Shareholders agreed not to sell, assign, offer to sell, contract, pledge, grant, or otherwise dispose of or enter into any swap or other similar arrangement, with respect to the Ordinary Shares they received in connection with the Business Combination for a period beginning on the Final Closing Date and ending one year after the Final Closing Date. Notwithstanding the foregoing, the restrictions above ended with respect to the Ordinary Shares held by the NewAmsterdam Pharma shareholders and 50% of the Ordinary Shares held by the FLAC Initial Shareholders, as the case may be, received in connection with the Business Combination, on May 22, 2023 according to the terms of the Investor Rights Agreement. The restrictions on the remaining 50% of the Ordinary Shares of the FLAC Initial Shareholders received in connection with the Business Combination ended on November 23, 2023, one year after the Final Closing Date. An aggregate of 44,914,642 Ordinary Shares held by former NewAmsterdam Pharma shareholders (including Amgen and MTPC) had registration rights pursuant to the terms of the Investor Rights Agreement.

In June 2023, certain of our selling securityholders (the "Selling Securityholders") exercised their right pursuant to the Investor Rights Agreement to demand an underwritten shelf takedown of Ordinary Shares. On June 6, 2023, the Company and certain of the Selling Securityholders, including affiliates of Forbion, entered into an Underwriting Agreement (the "Underwriting Agreement") with Jefferies LLC and SVB Securities LLC, as representatives of the several underwriters named therein (the "Underwriters"). The Underwriting Agreement related to an underwritten public offering of 13,857,415 Ordinary Shares by those certain Selling Securityholders at a public offering price of $11.50 per Ordinary Share (the "Secondary Offering"). In connection with the Secondary Offering, certain of the participating Selling Securityholders granted the Underwriters a 30-day option to purchase an additional 2,078,612 Ordinary Shares at the public offering price, less underwriting discounts and commissions, which option was partially exercised for 1,930,280 additional Ordinary Shares in connection with the closing of the Secondary Offering. The Company did not sell any Ordinary Shares in the Secondary Offering and did not receive any proceeds from the Secondary Offering.

Indemnification Agreements

The Articles of Association provide for certain indemnification rights for our current and former directors and other current and former officers and employees as designated by the Board of Directors (the "Indemnified Persons"). Specifically, we indemnify the Indemnified Persons against any financial losses or damages and any expense reasonably paid or incurred in connection with any threatened, pending or completed suit, to the extent these relate to such Indemnified Persons' current or former position with the Company as permitted by applicable law.

We have also entered into indemnification agreements with each of our directors and executive officers providing for procedures for indemnification and advancements by us of certain expenses and costs relating to claims, suits or proceedings arising from his or her service to us or, at our request, service to other entities, as officers or directors to the maximum extent permitted by Dutch law and subject to the exceptions provided in such agreements.

Employment Agreements

See the section titled "*Executive Compensation—Employment Agreements and Change of Control Agreements*" above for a further discussion of these arrangements.

Item 14. Principal Accountant Fees and Services

Principal Accountant Fees and Services

The following table presents the aggregate fees billed by Deloitte Accountants B.V. for the years ended December 31, 2024 and 2023.

	For the Years Ended December 31,	
(In thousands of USD)	**2024**	**2023**
Audit Fees	1,433	1,525
Audit-Related Fees	—	—
Tax Fees	—	—
All Other Fees	—	—
Total Fees	1,433	1,525

Audit fees include the standard audit work performed each fiscal year necessary to allow the auditor to issue an opinion on our financial statements and to issue an opinion on the local statutory financial statements. Audit fees also include services such as reviews of quarterly financial results and review of securities offering documents.

Audit-related fees consisted of fees billed for assurance and related services that were reasonably related to the performance of the audit or review of our financial statements or for services that were traditionally performed by the external auditor.

Tax fees are fees billed for professional services for tax compliance, tax advice and tax planning.

Audit Committee Pre-Approval Policies

The Audit Committee evaluates the qualifications, independence and performance of the independent auditor as well as pre-approves and reviews the engagement and the provision of all audit and non-audit services to be performed by the independent auditor. In accordance with this policy, all services performed by and fees paid to Deloitte Accountants B.V. were pre-approved by the Audit Committee.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(1) Financial Statements:

The Financial Statements required to be filed by Item 8 of this Annual Report, and filed in this Item 15, are as follows:

	Page
Report of Independent Registered Public Accounting Firm (Deloitte Accountants B.V.; PCAOB ID: 1243)	F-2
Consolidated Balance Sheets as at December 31, 2024 and 2023	F-3
Consolidated Statements of Operations and Comprehensive Income (Loss) for the Years Ended December 31, 2024, 2023 and 2022	F-4
Consolidated Statements of Mezzanine Equity and Shareholders' Equity (Deficit) for the Years Ended December 31, 2024, 2023 and 2022	F-5
Consolidated Statements of Cash Flows for the Years Ended December 31, 2024, 2023 and 2022	F-6
Notes to Consolidated Financial Statements	F-7

(2) Financial Statement Schedules:

Schedules are omitted because they are not applicable, or are not required, or because the information is included in the financial statements and notes thereto.

(3) Exhibits:

Exhibit No.	Description of Document
2.1	Business Combination Agreement, dated as of July 25, 2022, by and among Frazier Lifesciences Acquisition Corporation, NewAmsterdam Pharma Holding B.V., NewAmsterdam Pharma Company B.V. and NewAmsterdam Pharma Investment Corporation (incorporated by reference to Annex A to the Registration Statement on Form F-4 (File No. 333-266510), filed with the SEC on October 13, 2022).
2.2	Plan of Merger (incorporated by reference to Annex B to the Registration Statement on Form F-4 (File No. 333-266510), filed with the SEC on October 13, 2022).
3.1	English translation of the Deed of Conversion and Articles of Association of NewAmsterdam Pharma Company N.V. (incorporated by reference to Exhibit 1.1 to the Shell Company Report on Form 20-F (File No. 001-41562), filed with the SEC on November 28, 2022).
4.1	Warrant Assignment, Assumption and Amendment Agreement, among Continental Stock Transfer & Trust Company, NewAmsterdam Pharma Company B.V. and Frazier Lifesciences Acquisition Corporation (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form F-4 (File No. 333-266510), filed with the SEC on October 13, 2022).
4.2	Warrant Agreement, between Frazier Lifesciences Acquisition Corporation and Continental Stock Transfer & Trust Company (incorporated by reference to Exhibit 4.4 to the Registration Statement on Form S-1 (File No. 333-250858), filed by Frazier Lifesciences Acquisition Corporation with the SEC on November 20, 2020).
4.3	Warrant Certificate of NewAmsterdam Pharma Company N.V (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form F-4 (File No. 333-266510), filed with the SEC on October 13, 2022).
4.4	Description of Share Capital and Articles of Association.
10.1	Form of Subscription Agreement (incorporated by reference to Annex C to the Registration Statement on Form F-4 (File No. 333-266510), filed with the SEC on October 13, 2022).
10.2	Investor Rights Agreement, dated November 22, 2022, by and among NewAmsterdam Pharma Company N.V. and certain of its shareholders (incorporated by reference to Exhibit 10.5 to the Registration Statement on Form F-1 (File No. 333-268888), filed with the SEC on January 17, 2023).
10.3+	Form of Director & Officer Indemnity Agreement (incorporated by reference to Exhibit 10.7 to the Registration Statement on Form F-4 (File No. 333-266510), filed with the SEC on October 13, 2022).
10.4+	NewAmsterdam Pharma Company N.V. Long-term Incentive Plan (incorporated by reference to Exhibit 10.4 to the Annual Report on Form 10-K, filed with the SEC on February 28, 2024).
10.5+	NewAmsterdam Pharma Company N.V. Rollover Option Plan (incorporated by reference to Exhibit 4.16 to the Shell Company Report on Form 20-F (File No. 001-41562), filed with the SEC on November 28, 2022).
10.6+	NewAmsterdam Pharma Company N.V. Supplementary Long-term Incentive Plan (incorporated by reference to Exhibit 10.15 to the Registration Statement on Form F-1 (File No. 333-268888), filed with the SEC on January 17, 2023).
10.7+	NewAmsterdam Pharma Company N.V. Inducement Plan (incorporated by reference to Exhibit 99.2 to the Registration Statement on Form S-8 (File No. 333-280689), filed with the SEC on July 3, 2024).

10.8+*	Employment Agreement, dated January 25, 2023, between NewAmsterdam Pharma Corporation and Michael Davidson (incorporated by reference to Exhibit 10.7 to the Annual Report on Form 10-K, filed with the SEC on February 28, 2024).
10.9+*	Employment Agreement, dated November 18, 2022, between NewAmsterdam Pharma B.V. and John Kastelein (incorporated by reference to Exhibit 10.8 to the Annual Report on Form 10-K, filed with the SEC on February 28, 2024).
10.10+*	Employment Agreement, dated October 6, 2023, between NewAmsterdam Pharma Corporation and Ian Somaiya (incorporated by reference to Exhibit 10.9 to the Annual Report on Form 10-K, filed with the SEC on February 28, 2024).
10.11+*	Employment Agreement, dated March 22, 2024, between Globalization Partners Switzerland SA and Juliette Audet.
10.12+	Letter Agreement, dated March 22, 2024, between NewAmsterdam Pharma Company N.V. and Juliette Audet.
10.13+*	Employment Agreement, dated January 24, 2023, between NewAmsterdam Pharma Corporation and Douglas Kling.
10.14+	Form of Option Award Agreement (incorporated by reference to Exhibit 10.10 to the Annual Report on Form 10-K, filed with the SEC on February 28, 2024).
10.15†	License Agreement, dated June 23, 2022, between A. Menarini International Licensing S.A. and NewAmsterdam Pharma B.V. (incorporated by reference to Exhibit 10.8 to the Registration Statement on Form F-4/A (File No. 333-266510), filed with the SEC on September 13, 2022).
10.16†	Amendment to License Agreement, dated January 15, 2024, between NewAmsterdam Pharma B.V. and A. Menarini International Licensing S.A.
19.1	Insider Trading Policy of the Company
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 to the Registration Statement on Form F-1 (File No. 333-268888), filed with the SEC on January 17, 2023).
23.1	Consent of Deloitte Accountant B.V., independent registered public accounting firm.
24.1	Power of Attorney (incorporated by reference to the signature page of this Annual Report on Form 10-K).
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Policy Relating to Recovery of Erroneously Awarded Compensation of NewAmsterdam Pharma Company N.V. (incorporated by reference to Exhibit 97.1 to the Annual Report on Form 10-K, filed with the SEC on February 28, 2024).
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File-the cover page interactive data is embedded within the Inline XBRL document or included within the Exhibit 101 attachments

+ Indicates management contract or compensatory plan.

* Portions of this document (indicated by "[***]") have been omitted in accordance with Item 601(a)(5) of Regulation S-K.

† Portions of this document (indicated by "[***]") have been omitted in accordance with Item 601(b)(10)(iv) of Regulation S-K because such information is not material and is the type of information that the registrant treats as private or confidential.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NewAmsterdam Pharma Company N.V.

Date: February 26, 2025

By: /s/ Michael Davidson
Michael Davidson, M.D.
Chief Executive Officer and Director
(Principal Executive Officer)

Date: February 26, 2025

By: /s/ Ian Somaiya
Ian Somaiya
Chief Financial Officer
(Principal Financial Officer)

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Michael Davidson and Ian Somaiya, jointly and severally, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her, and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorneys-in-fact and agents, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Michael Davidson Dr. Michael Davidson	Chief Executive Officer and Director *(Principal Executive Officer)*	February 26, 2025
/s/ Ian Somaiya Ian Somaiya	Chief Financial Officer *(Principal Financial Officer)*	February 26, 2025
/s/ Louise Kooij Louise Kooij	Chief Accounting Officer (*Principal Accounting Officer*)	February 26, 2025
/s/ William H. Lewis William H. Lewis	Chair and Director	February 26, 2025
/s/ Nicholas S. Downing Dr. Nicholas S. Downing	Director	February 26, 2025
/s/ John Kastelein Dr. John Kastelein	Chief Scientific Officer, Director	February 26, 2025
/s/ Wouter Joustra Wouter Joustra	Director	February 26, 2025
/s/ Louis Lange Dr. Louis Lange	Director	February 26, 2025
/s/ Mark C. McKenna Mark C. McKenna	Director	February 26, 2025
/s/ John W. Smither John W. Smither	Director	February 26, 2025
/s/ James N. Topper Dr. James N. Topper	Director	February 26, 2025
/s/ Janneke van der Kamp Janneke van der Kamp	Director	February 26, 2025

NewAmsterdam Pharma Company N.V.
Index to Financial Statements

	Page
Report of Independent Registered Public Accounting Firm (Deloitte Accountants B.V.; PCAOB ID: 1243)	F-2
Consolidated Balance Sheets as at December 31, 2024 and 2023	F-5
Consolidated Statements of Operations and Comprehensive Income (Loss) for the Years Ended December 31, 2024, 2023 and 2022	F-6
Consolidated Statements of Mezzanine Equity and Shareholders' Equity (Deficit) for the Years Ended December 31, 2024, 2023 and 2022	F-7
Consolidated Statements of Cash Flows for the Years Ended December 31, 2024, 2023 and 2022	F-8
Notes to Consolidated Financial Statements	F-9

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of NewAmsterdam Pharma Company N.V.

Opinion on the Financial Statements

We have audited the accompanying Consolidated Balance Sheets of NewAmsterdam Pharma Company N.V. and subsidiaries (the "Company") as of December 31, 2024 and 2023, the related Consolidated Statements of Operations and Comprehensive Income (Loss), Mezzanine Equity and Shareholders' Equity (Deficit) and Cash Flows, for each of the three years in the period ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 26, 2025, expressed an unqualified opinion on the Company's internal control over financial reporting.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Research and development accruals and prepayments – Refer to Notes 2, 7 and 8 to the financial statements

Critical 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 critical audit matter because of the significant judgment 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 judgment 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 Critical 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.

/s/ Deloitte Accountants B.V.

Eindhoven, The Netherlands

February 26, 2025

We have served as the Company's auditor since 2020.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of NewAmsterdam Pharma Company N.V.

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of NewAmsterdam Pharma Company N.V. and subsidiaries (the "Company") as of December 31, 2024, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control — Integrated Framework (2013) issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2024, of the Company and our report dated February 26, 2025, expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Deloitte Accountants B.V.

Eindhoven, The Netherlands

February 26, 2025

NewAmsterdam Pharma Company N.V.
Consolidated Balance Sheets

(In thousands of USD)	As at December 31, 2024	2023
Assets		
Current assets:		
Cash and cash equivalents	771,743	340,450
Prepayments and other receivables	24,272	6,341
Employee receivables	4,951	—
Marketable securities	62,447	—
Total current assets	863,413	346,791
Property, plant and equipment, net	242	46
Operating right of use asset	431	55
Intangible assets	534	170
Long term prepaid expenses	—	35
Total assets	864,620	347,097
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	4,744	16,923
Accrued expenses and other current liabilities	13,608	11,398
Deferred revenue, current	6,008	8,942
Lease liability, current	246	60
Derivative earnout liability, current	44,798	—
Derivative warrant liabilities	37,514	12,574
Total current liabilities	106,918	49,897
Deferred revenue, net of current portion	—	1,019
Lease liability, net of current portion	202	—
Derivative earnout liability, net of current portion	—	7,788
Total liabilities	107,120	58,704
Commitments and contingencies (Note 13)		
Shareholders' Equity:		
Ordinary shares, €0.12 par value; 400,000,000 shares authorized; 108,064,340 and 82,469,768 shares issued and outstanding at December 31, 2024 and 2023, respectively	13,444	10,173
Additional paid-in capital	1,298,160	590,771
Accumulated loss	(558,571)	(316,973)
Accumulated other comprehensive income	4,467	4,422
Total shareholders' equity	757,500	288,393
Total liabilities and shareholders' equity	864,620	347,097

See notes to consolidated financial statements.

NewAmsterdam Pharma Company N.V.
Consolidated Statements of Operations and Comprehensive Income (Loss)

(In thousands of USD, except per share amounts)	For the year ended December 31, 2024	2023	2022
Revenue	45,563	14,090	102,694
Operating expenses:			
Research and development expenses	151,406	159,424	86,744
Selling, general and administrative expenses	70,446	37,633	19,507
Total operating expenses	221,852	197,057	106,251
Operating loss	(176,289)	(182,967)	(3,557)
Other income (expense):			
Interest income	16,881	11,283	—
Interest expense	—	—	(287)
Fair value change – earnout	(37,010)	(266)	(707)
Fair value change – warrants	(38,583)	(10,018)	(334)
Fair value change – profit rights	—	—	(12,390)
Fair value change – tranche rights	—	—	4,388
Foreign exchange gains/(losses)	(6,598)	5,058	(9,747)
Loss before tax	(241,599)	(176,910)	(22,634)
Income tax expense (benefit)	(1)	27	—
Loss for the year	(241,598)	(176,937)	(22,634)
Other comprehensive income/(loss)			
Foreign currency translation adjustments	—	—	11,126
Unrealized gain on available-for-sale securities	45	—	—
Income tax effects of other comprehensive income/(loss)	—	—	—
Total comprehensive loss for the year, net of tax	(241,553)	(176,937)	(11,508)
Net loss per ordinary share			
Basic and diluted	$ (2.56)	$ (2.15)	$ (1.19)

See notes to consolidated financial statements.

NewAmsterdam Pharma Company N.V.
Consolidated Statements of Mezzanine Equity and Shareholders' Equity (Deficit)

	Mezzanine Equity		Shareholders' Equity					
(In thousands of USD, except share amounts)	**Shares**	**Amount**	**Shares**	**Amount**	**Additional Paid-In Capital**	**Accumulated Loss**	**Accumulated other comprehensive income (loss)**	**Total Shareholders' Equity**
Opening balance at January 1, 2022	6,039,728	84,541	5,285,714	58	3,417	(110,587)	(6,704)	(113,816)
Equity contribution (Series A - Tranche II)	5,691,430	90,468	—	—	—	—	—	—
Repayment of loan (CEO Restricted Share Award)	—	—	—	—	747	—	—	747
Elimination of old shares (NewAmsterdam Pharma shareholders)	(11,731,158)	(175,009)	(5,285,714)	(58)	(4,164)	—	—	(4,222)
Equity contribution (NewAmsterdam Pharma shareholders)	—	—	36,258,312	4,470	174,761	—	—	179,231
Equity contribution (FLAC shareholders)	—	—	13,185,138	1,625	66,252	—	—	67,877
Equity contribution (PIPE Financing)	—	—	23,460,000	2,892	231,708	—	—	234,600
Equity contribution (Amgen & MTPC shareholders)	—	—	8,656,330	1,068	84,371	—	—	85,439
Transaction costs on issue of shares	—	—	—	—	(5,794)	—	—	(5,794)
Earnout obligation upon Closing (NewAmsterdam Pharma shareholders)	—	—	—	—	—	(6,815)	—	(6,815)
Share-based compensation	—	—	—	—	4,327	—	—	4,327
Total profit or loss and comprehensive loss for the year	—	—	—	—	—	(22,634)	11,126	(11,508)
As at December 31, 2022	—	—	81,559,780	10,055	555,625	(140,036)	4,422	430,066
Exercise of warrants	—	—	749,741	97	10,116	—	—	10,213
Exercise of stock options	—	—	160,247	21	269	—	—	290
Share-based compensation	—	—	—	—	24,761	—	—	24,761
Total profit or loss and comprehensive loss for the year	—	—	—	—	—	(176,937)	—	(176,937)
As at December 31, 2023	—	—	82,469,768	10,173	590,771	(316,973)	4,422	288,393
February 2024 Issuance of Ordinary Shares and Pre-Funded Warrants, net of issuance costs	—	—	5,871,909	759	189,206	—	—	189,965
December 2024 Issuance of Ordinary Shares and Pre-Funded Warrants, net of issuance costs			14,667,347	1,851	451,564	—	—	453,415
Exercise of Pre-Funded Warrants	—	—	2,105,248	279	(279)	—	—	-
Exercise of warrants	—	—	1,288,790	168	27,673	—	—	27,841
Exercise of stock options	—	—	1,661,278	214	5,496	—	—	5,710
Share-based compensation	—	—	—	—	33,729	—	—	33,729
Total loss and comprehensive loss for the period	—	—	—	—	—	(241,598)	45	(241,553)
As at December 31, 2024	—	—	108,064,340	13,444	1,298,160	(558,571)	4,467	757,500

See notes to consolidated financial statements.

NewAmsterdam Pharma Company N.V.
Consolidated Statements of Cash Flows

(In thousands of USD)	For the year ended December 31, 2024	2023	2022
Operating activities:			
Loss for the year	(241,598)	(176,937)	(22,634)
Non-cash adjustments to reconcile loss before tax to net cash flows:			
Depreciation and amortization	113	49	9
Non-cash rent expense	12	6	10
Fair value change - tranche rights	—	—	(4,388)
Fair value change - IPR&D	—	—	12,390
Fair value change - derivative earnout and warrants	75,593	10,284	1,041
Foreign exchange (gains)/losses	6,598	(5,058)	9,747
Amortization of premium/discount on available-for-sale debt securities	(227)	—	—
Share-based compensation	33,619	24,572	4,117
Changes in working capital:			
Changes in prepayments (current and non-current) and other receivables	(17,459)	4,031	(4,185)
Changes in accounts payable	(12,948)	5,070	4,809
Changes in accrued expenses and other current liabilities	1,686	5,470	(8,679)
Changes in deferred revenue	(3,953)	(8,705)	18,428
Net cash (used in)/provided by operating activities	**(158,564)**	**(141,218)**	**10,665**
Investing activities:			
Purchase of property, plant and equipment, including internal use software	(672)	(24)	(221)
Purchase of available-for-sale debt securities	(62,176)	—	—
Net cash used in investing activities	**(62,848)**	**(24)**	**(221)**
Financing activities:			
Proceeds from issuing equity securities (Series A)	—	—	90,469
Proceeds from issuing equity securities (FLAC shareholders)	—	—	71,883
Proceeds from issuing equity securities (PIPE Financing)	—	—	234,600
Transaction costs on issue of equity securities	—	—	(5,794)
Proceeds from payment of shareholder loan	—	—	747
Proceeds from February 2024 offering of Ordinary Shares and Pre-Funded Warrants	190,481	—	—
Transaction costs on February 2024 issue of Ordinary Shares and Pre-Funded Warrants	(515)	—	—
Proceeds from December 2024 offering of Ordinary Shares and Pre-Funded Warrants	455,026	—	—
Transaction costs on December 2024 issue of Ordinary Shares and Pre-Funded Warrants	(25)	—	—
Proceeds from exercise of warrants	13,761	8,622	—
Proceeds from exercise of options	1,768	290	—
Payment of withholding taxes related to net share settlement of exercised options	(989)	—	—
Net cash provided by financing activities	**659,507**	**8,912**	**391,905**
Net change in cash and cash equivalents	438,095	(132,330)	402,349
Foreign exchange differences	(6,802)	5,052	5,248
Cash and cash equivalents at the beginning of the year	340,450	467,728	60,131
Cash and cash equivalents at the end of the year	**771,743**	**340,450**	**467,728**
Noncash financing and investing activities			
Derivative earnout obligation recognized related to the Business Combination (as defined in Note 3)	—	—	6,815
Liabilities assumed in the Business Combination (as defined in Note 3)	—	—	(4,006)
Contribution of interest in NewAmsterdam Pharma Holding B.V. by Participating Shareholders (as defined in Note 3)	—	—	(179,231)
Issuance of Ordinary Shares to Participating Shareholders (as defined in Note 3)	—	—	179,231
Recognition of ROU asset	562	—	—
Supplemental cash flow disclosures			
Cash paid for interest	—	—	277
Cash paid for income taxes	1	27	—

See notes to consolidated financial statements

NewAmsterdam Pharma Company N.V.
Notes to Consolidated Financial Statements

Note 1. The Company

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 ("FLAC") as described in Note 3. 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.

Going Concern

The Company has incurred net operating losses and negative cash flows from operations since its inception and had an accumulated deficit of $558.6 million as of December 31, 2024. As of December 31, 2024 the Company had cash and cash equivalents of $771.7 million. Management believes that the existing financial resources are sufficient to continue operating activities for at least the twelve-month period following the issuance of these consolidated financial statements.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") and the rules and regulations of the U.S. Securities and Exchange Commission ("SEC"). Any reference in these notes to the applicable guidance is meant to refer to authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB"). The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, after elimination of intercompany accounts and transactions.

Functional and Reporting Currency

The functional currency of the Company and its subsidiaries has been the United States Dollar ("USD" or "$") since January 1, 2023. Prior to that the functional currency of the Company and its subsidiaries was the Euro ("EUR" or "€"). Significant elements involved in the determination of the functional currency change included a shift in the Company's sources of financing from EUR to USD given its access to the U.S. public market and an increase of

operating costs incurred in USD due to Phase 3 trials taking place predominantly in the United States, among other factors. Given these significant changes, management concluded that the majority of the factors supported the determination of the USD as the functional currency.

The reporting currency of the Company is USD.

Consolidation

The consolidated financial statements comprise the financial statements of the Company and its subsidiaries. Subsidiaries are all entities over which the Company has a controlling financial interest either through variable interest or through voting interest. Currently, the Company has no involvement with variable interest entities and all subsidiaries are wholly-owned. Intercompany transactions, balances, income, and expenses are eliminated in consolidation. Profits and losses resulting from intercompany transactions that are recognized in assets are also eliminated.

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, assumptions related to the Company's revenue recognition, accrual of research and development expenses, valuation of stock option awards and valuation of derivative instruments. The Company based its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates when there are changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. If actual results differ from the Company's estimates, or to the extent these estimates are adjusted in future periods, the Company's results of operations could either benefit from, or be adversely affected by, any such change in estimate.

Fair Value Measurements

Certain assets and liabilities of the Company are carried at fair value under U.S. GAAP either upon initial recognition or for subsequent accounting and reporting. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 – Inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.
- Level 2 – Valuations based on quoted prices in markets that are not active or for which all significant inputs are observable, either directly or indirectly.
- Level 3 – Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

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 Company 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.

Segment Information

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company's chief operating decision maker is the chief executive officer. The Company has one business activity and there are no segment managers who are held accountable for operations, operating results, and plans for levels or components below the consolidated unit level. Accordingly, the Company has one operating segment and, therefore, one reportable segment, which comprises the discovery, development and commercialization of transformative therapies for cardio-metabolic diseases.

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 stated at fair value, 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, 2023 and 2022, the Company did not have any realized gains or losses on marketable securities.

Property Plant and Equipment, Net

Property and equipment are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method and is recorded in Selling, general, and administrative expense over the estimated useful lives of the assets. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed as incurred. Upon disposal of an asset, the related cost and accumulated depreciation is removed from the accounts and any resulting gain or loss on the transaction is recognized.

The estimated useful lives of property and equipment are as follows:

	Estimated Useful Life (in years)
Computer equipment	5
Office furniture and equipment	5

Impairment of Long-Lived Assets

The Company reviews the recoverability of its long-lived assets when events or changes in circumstances occur that indicate that the carrying value of the asset may not be recoverable. The assessment of possible impairment is based on the ability to recover the carrying value of the assets from the expected future cash flows (undiscounted and without interest expense) of the related operations. If these cash flows are less than the carrying value of such assets, an impairment loss for the difference between the estimated fair value and carrying value is recorded. To date, the Company has not recorded any material impairment losses on long-lived assets.

Leases

In accordance with ASU No. 2016-02, Leases (Topic 842) ("ASU 2016-02" or "ASC 842"), the Company classifies leases at the lease commencement date. At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the circumstances present. Leases with a term greater than one year will be recognized on the consolidated balance sheets as right-of-use assets ("ROU"), lease liabilities, and if applicable, long-term lease liabilities. The Company includes renewal options to extend the lease in the lease term where it is reasonably certain that it will exercise these options. Lease liabilities and the corresponding ROU are recorded based on the present values of lease payments over the terms. The Company determines the discount rate based on the implicit rate in the contract and if not readily determinable, the Company utilizes the appropriate incremental borrowing rates, which are the rates that would be incurred to borrow on a collateralized basis, over similar terms, amounts equal to the lease payments in a similar economic environment. Variable payments that do not depend on a rate or index are not included in the lease liability and are recognized as incurred. Lease contracts do not include residual value guarantees nor do they include restrictions or other covenants. Certain adjustments to ROUs may be required for items such as initial direct costs paid, incentives received, or lease prepayments. If significant events, changes in circumstances, or other events indicate that the lease term or other inputs have changed, the Company would reassess lease classification, remeasure the lease liability using revised inputs as of the reassessment date, and adjust the ROU. Lease agreements with a noncancelable term of less than 12 months and no purchase option that the Company is reasonably certain to exercise are not recorded on the Company's consolidated balance sheet. Costs related to such lease agreements are operating cash flows and recorded in selling, general and administrative expenses.

Derivative Warrants Liability

The Company accounts for the public warrants and private placement warrants in accordance with the guidance contained in ASC 480, *Distinguishing Liabilities from Equity* ASC 815-40, *Derivatives and Hedging—Contracts in Entity's Own Equity*, under which the public warrants and private placement warrants do not meet the criteria for equity treatment and must be recorded as liabilities carried at fair value. This liability is subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized as (expense)/income in the consolidated statements of operations and comprehensive loss. The public warrants are valued based on the quoted market price as of each relevant reporting date, which is a Level 1 fair value measurement. The private warrants were initially and subsequently determined to have value equal to the public warrants as the terms of the instruments are substantially equivalent. The valuation of the private warrants is considered to be a Level 2 fair value measurement.

Derivative Earnout Liability

The Company accounts for the Earnout Shares (as defined below) allocated to Participating Shareholders (as defined below) in accordance with the guidance contained in ASC 480, *Distinguishing Liabilities from Equity* ASC 815-40, *Derivatives and Hedging—Contracts in Entity's Own Equity*, under which the Earnout Shares allocated to Participating Shareholders do not meet the criteria for equity treatment and must be recorded as liabilities carried at fair value. This liability is subject to re-measurement at each balance sheet date until exercised, and any change in

fair value is recognized as (expense)/income in the consolidated statements of operations and comprehensive loss. The liability is valued utilizing the Black-Scholes model, taking into account the probability of achieving the applicable milestone. The valuation of the Earnout Shares allocated to Participating Shareholders is considered to be a Level 3 fair value measurement.

Tranche Rights

On December 30, 2020, we entered into the Series A Subscription Agreement to issue Series A Preferred Shares for up to an aggregate amount of €160 million, occurring in two tranches. The first tranche closed in January 2021 (the "First Closing"). The Series A subscription agreement entitled us to cause the investors to subscribe for the second tranche Series A Preferred Shares upon the occurrence of certain clinical development and business development milestones.

As part of the Series A subscription agreement, investors were entitled to participate in the second tranche earlier, if they elect. This tranche right was determined to be a "freestanding financial instrument" as defined in the ASC Master Glossary because the tranche rights were transferable, and they did not need to be transferred with the related Series A shares. Further, upon the exercise of tranche rights, Series A shares held by investors remain outstanding. Management assessed the freestanding financial instrument under ASC 480, *Distinguishing Liabilities from Equity*, and determined that the tranche rights should be accounted for as a liability at fair value and revalued at each reporting period until settlement, with changes in the fair value recorded in the consolidated statements of operations and comprehensive loss. This determination was made because the tranche rights were exercisable at the investor's election, and therefore future issuance of Series A shares were a contingent event that was not in the Company's control.

We issued the second tranche of Series A Preferred Shares in February 2022. This exercise of the tranche rights resulted in cash proceeds to the company, derecognition of the tranche right liability, and Series A Preferred Shares recognized at fair value, with the difference recorded to the consolidated statements of operations and comprehensive loss.

Profit rights - Dezima acquisition

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

The Company evaluates acquisitions of assets and other similar transactions in accordance with ASC 805, Business Combinations, to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen is met, the transaction is accounted for as an asset acquisition. The acquisition of Dezima was accounted for as an asset acquisition because substantially all of the fair value of the gross assets acquired is concentrated in the IPR&D of Obicetrapib. Additionally, the Company determined that as of the acquisition date, the IPR&D did not have an alternative future use by which the economic benefits could be anticipated and estimated. Therefore, it did not meet the definition of an asset and was expensed as incurred.

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. These rights were recognized as a contingent consideration liability. Contingent consideration in an asset acquisition is measured and recognized when payment becomes probable and a reliable estimate can be made. Subsequent changes in the accrued amount of

contingent consideration are measured and recognized at the end of each reporting period and upon settlement as an adjustment to the cost basis of the acquired asset or group of assets. However, as the acquired asset in the Dezima transaction was IPR&D with no alternative future use, any adjustment to the cost is expensed during the period and not capitalized.

The execution of the Menarini License (as defined in Note 4), in combination with the FLAC Merger (as defined in Note 3), qualified as an exit event pursuant to the 2020 SPA. As a result, on the Closing Date (as defined in Note 3), pursuant to the Profit Right Agreement, Amgen and MTPC each received their respective contingent payments in the form of Ordinary Shares. Immediately prior to the closing of the Business Combination, the value of the financial liability was adjusted to equal the fair value of the Ordinary Shares to be issued to Amgen and MPTC at the closing of the Business Combination with the change in fair value recognized through earnings in the consolidated statement of operations and comprehensive loss. Finally, the liability was derecognized with the corresponding offset to equity to record the issuance of the Ordinary Shares to Amgen and MTPC.

Revenue Recognition

The Company recognizes revenue in accordance with ASU 2014-09, *Revenue from Contracts with Customers*, and subsequent amendments (collectively, "ASC 606").

Under ASC 606, 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.

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 research and development activities may not be entirely certain. In estimating progress toward completion of specific tasks, the Company 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 Company personnel.

The costs of intangibles that are purchased from others for a particular research and development project and that have no alternative future uses are expensed as research and development costs at the time the costs are incurred or at the time when no alternative future use is identified.

Selling, General and Administrative Expenses

Expenses are recognized on the accrual basis when incurred.

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 Company'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 statement of operations and comprehensive loss in the period in which they are incurred, and outstanding contributions are included in trade and other payables.

Share-Based Compensation

The Company accounts for its share-based compensation in accordance with ASC 178 – *Compensation – Stock Compensation* ("ASC 718"). Share-based compensation is measured based on the grant date fair value of the equity awards using the Black-Scholes option pricing model. Share-based compensation expense is recognized on a straight-line basis over the requisite service period of the awards. Forfeitures and modifications are accounted for as they occur. The Company classifies share-based compensation expense in its consolidated statement of operations and comprehensive loss in the same manner in which the award recipient's salary and related costs are classified.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of Ordinary Shares outstanding during the period. For the purposes of calculating the weighted-average number of Ordinary Shares outstanding, the Ordinary Shares underlying the Pre-Funded Warrants issued in the February 2024 Offering and the December 2024 Offering (as defined in Note 9 below) are included. Diluted net loss per share is the same as basic net loss per share, since the effects of potentially dilutive securities are antidilutive given the net loss for each period presented.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the consolidated financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies. The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

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 reporting 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).

Recently Issued Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures" which requires entities to enhance disclosures around segment reporting. The guidance is effective for annual periods beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company adopted and applied the amendments of this ASU to its disclosures. The application of this ASU did not have a material impact on the Company's financial position, results of operations or cash flows.

In December 2023, the FASB issued ASU 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures" which requires entities to enhance disclosures around income taxes. The guidance is effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the effect this standard will have on its consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU 2024-03, "Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40)" which requires entities to enhance disclosures around the nature of expenses included in the income statement. The guidance is effective for annual periods beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the effect this standard will have on its consolidated financial statements and related disclosures.

Note 3. FLAC Merger

Prior to November 22, 2022, NewAmsterdam Pharma Company N.V. was a shell company with no active trade or business, and all relevant assets and liabilities, as well as income and expenses, were borne by NewAmsterdam Pharma Holding B.V. FLAC was a special purpose acquisition company incorporated on October 7, 2020 as a Cayman Islands exempted company formed for the purpose of effecting a merger, share exchange, asset acquisition, share purchase, reorganization or a similar business combination. FLAC completed its initial public offering on December 11, 2020 and listed on the Nasdaq.

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

On November 22, 2022 (the "Closing Date"), Pursuant to the terms of the Business Combination Agreement, the following transactions occurred (collectively, the "Business Combination").

- On the date prior to the Closing Date, the shareholders of NewAmsterdam Pharma Holding B.V. ("Participating Shareholders") exchanged their interest for Ordinary Shares such that the Company became the direct parent of NewAmsterdam Pharma Holding B.V. (the "Exchange"). In connection with the Exchange, 17,016,872 NewAmsterdam Pharma Holding B.V. shares of €0.01 par value were exchanged at a ratio of approximately 2.13 for 36,258,312 Ordinary Shares, €0.12 par value per share.

- Immediately after giving effect to the Exchange, a subsidiary of the Company merged with and into FLAC (the "Merger"), with FLAC surviving as a wholly owned subsidiary of the Company.

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

•Each NewAmsterdam Pharma Holding B.V. option that was outstanding and unexercised remained outstanding, and to the extent unvested, such option will continue to vest in accordance with its applicable terms, and at the time of the Exchange, such NewAmsterdam Pharma Holding B.V. options became options to purchase, and will when exercised be settled in Ordinary Shares.

•In addition to the transactions described above, 8,656,330 Ordinary Shares were issued to Amgen and MTPC pursuant to their profit rights granted upon the acquisition of Dezima.

The Business Combination was accounted for as a reverse recapitalization in accordance with U.S. GAAP. Under this method of accounting FLAC was treated as the acquired company for financial reporting purposes. This determination is primarily based on the fact that subsequent to the Business Combination, NewAmsterdam Pharma Holding B.V.'s shareholders had the majority of the voting power of the combined entity, NewAmsterdam Pharma Holding B.V. comprised all of the ongoing operations of the combined entity, NewAmsterdam Pharma Holding B.V.'s shareholders had the ability to appoint a majority of the governing body of the combined entity, and NewAmsterdam Pharma Holding B.V.'s senior management comprised all of the senior management of the combined entity. Accordingly, for accounting purposes, the Business Combination was treated as the equivalent of the Company, immediately following the Exchange, issuing shares for the net assets of FLAC. As of the Closing Date the net assets of FLAC totaled $67.9 million which consisted of $71.9 million of cash, less liabilities assumed of $4.0 million. The Company provided consideration with fair value of $130.1 million in the form of Ordinary Shares. The difference between consideration paid and net assets acquired is recorded within additional paid in capital. No goodwill or intangibles were recorded. Operations prior to the Business Combination are those of NewAmsterdam Pharma Holding B.V.

Following the Merger, upon the achievement of a certain clinical development milestone, the Company will issue to the Participating Shareholders, Amgen, MTPC and holders of options to purchase shares of NewAmsterdam Pharma Holding B.V. prior to the closing of the Business Combination, who were directors, officers, employees or consultants of NewAmsterdam Pharma as of the date of the Business Combination Agreement and who are at the time of achievement of such milestone still providing services to the Company (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.

The Company raised an additional $234.6 million in net equity proceeds through a private placement of Ordinary Shares with existing shareholders of NewAmsterdam Pharma Holding B.V., FLAC and other new investors (the "PIPE Financing").

Both the Merger and PIPE Financing closed as of November 22, 2022. Upon consummation of the transactions, the Company's Ordinary Shares began trading on the Nasdaq under the ticker NAMS. The Public Warrants are traded under the ticker NAMSW. The Company also amended existing share-based compensation agreements held by employees of NewAmsterdam Pharma Holding B.V. prior to the Merger in addition to making additional share-based payments.

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 ASC 606.

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 ASC 606 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 was 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, €30 million of which has been received as of December 31, 2024. These milestones are contingent payments that represent variable consideration that are not initially recognized within the transaction price, due to the scientific uncertainties around the continued development and 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 ASC 606, 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:

	Year ended December 31,		
(In thousands of USD)	**2024**	**2023**	**2022**
License revenue attributed from license performance obligation	27,325	5,385	98,613
License revenue attributed from R&D performance obligation	18,238	8,705	4,081
Total revenue	45,563	14,090	102,694

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

(In thousands of USD)	**2024**	**2023**
Beginning balance on January 1	9,961	18,666
Addition of deferred revenue under the Menarini License	2,412	—
Revenue recognized under the Menarini License during the period	(6,365)	(8,705)
Ending balance on December 31	6,008	9,961

Note 5. Cash, cash equivalents and marketable securities

A summary of cash, cash equivalents and marketable securities held by the Company as of December 31, 2024 and 2023 is as follows:

	As at December 31, 2024			
(In thousands of USD)	**Amortized Cost**	**Unrealized gains**	**Unrealized losses**	**Fair Value**
Cash and cash equivalents:				
Cash	733,826	—	—	733,826
Money market funds (Level 1)	25,444	—	—	25,444
US government agency securities (Level 2)	12,473	—	—	12,473
Total cash and cash equivalents	771,743	—	—	771,743
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

	As at December 31, 2023			
(In thousands of USD)	**Amortized Cost**	**Unrealized gains**	**Unrealized losses**	**Fair Value**
Cash and cash equivalents:				
Cash	340,450	—	—	340,450
Total cash and cash equivalents	340,450	—	—	340,450

Note 6. Fair Value Measurements

As of December 31, 2024 and 2023, the Company's financial liabilities recognized at fair value on a recurring basis consisted of the following:

	As at 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	—	—	44,798	44,798
Total financial liabilities	35,134	2,380	44,798	82,312

	As at 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

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. 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 entirely 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 such, the relevant 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

During the year ended December 31, 2024 the Company announced positive topline results from its Phase 3 BROOKLYN and BROADWAY clinical trials. Completion of and positive results from the BROOKLYN and BROADWAY trials are the main components of the milestone which is required in order for the Earnout Shares to be issued, excepting completion of certain study reports. The Company has determined that the completion of the BROOKLYN and BROADWAY clinical trial with both clinical trials meeting their primary endpoints increases the estimated probability of achieving the milestone from 40% as of December 31, 2023 to 100% as of December 31, 2024.

The following table presents a reconciliation of the earnout liability measured on a recurring basis using Level 3 inputs as of December 31, 2024 and 2023:

Balance on December 31, 2022	7,522
Change in fair value recognized through earnings	266
Balance on December 31, 2023	7,788

Balance on December 31, 2023	7,788
Change in fair value recognized through earnings	37,010
Balance on December 31, 2024	44,798

All changes in fair value recognized in the statement of operations are unrealized. There were no sales, purchases, settlements or transfers into or out of Level 3 of the fair value hierarchy related to the earnout liability during the years ended December 31, 2024 and 2023.

Note 7. Prepayments and Other Receivables

Prepayments and other receivables consisted of the following:

	As at December 31,	
(In thousands of USD)	**2024**	**2023**
Prepaid research and development costs	5,704	2,337
Other prepaid expenses	2,214	2,123
License fee receivable	14,285	—
Value added tax receivable	321	1,006
Other receivables	1,748	875
Total prepayments and other receivables	24,272	6,341

Note 8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	As at December 31,	
(in thousands of USD)	**2024**	**2023**
Accrued research and development materials and services	2,069	5,945
Accrued compensation and benefits	8,721	3,384
Accrued professional fees and other	2,818	2,069
Total accrued expenses and other current liabilities	13,608	11,398

Note 9. Shareholders' Equity

The Company has an authorized share capital of 400,000,000 Ordinary Shares each with a nominal value of €0.12. The following summarizes the main rights of holders of Ordinary Shares:

- each holder of Ordinary Shares is entitled to one vote per share on all matters to be voted on by shareholders generally, including the appointment of our directors;
- there are no cumulative voting rights;
- the holders of Ordinary Shares are entitled to dividends and other distributions as may be declared from time to time by us out of funds legally available for that purpose, if any;
- upon our liquidation and dissolution, the holders of Ordinary Shares will be entitled to share ratably in the distribution of all of our assets remaining available for distribution after satisfaction of all our liabilities; and
- the holders of Ordinary Shares have pre-emption rights in case of share issuances or the grant of rights to subscribe for shares, except if such rights are limited or excluded by the corporate body authorized to do so and except in such cases as provided by Dutch law and the Articles of Association

FLAC Merger

On November 21, 2022 in connection with the Exchange, as described in Note 3, all the outstanding share capital of NewAmsterdam Pharma Holding B.V., consisting of 11,731,158 Series A Preferred Shares and 5,285,714 ordinary shares, was exchanged for Ordinary Shares of the Company at a ratio of approximately 2.13 per share. The Series A Preferred Shares were classified in accordance with ASC 480, *Distinguishing Liabilities from Equity* which required that the shares be classified outside of permanent shareholders' equity. Accordingly, the Series A Preferred Shares were classified as Mezzanine Equity in the applicable periods.

February 2024 Follow-on Offering

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.

December 2024 Follow-on Offering

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.

Employee Receivables Due Upon Exercise of Company Options

As of December 31, 2024 the amount reported on the consolidated balance sheet for employee receivables included amounts which were due to the Company for Company Options which had been exercised, but for which the exercise price had not yet been remitted. All such receivables were paid to the Company prior to the issuance of this report.

As of December 31, 2024 and 2023 only Ordinary Shares were outstanding or authorized.

Note 10. Share-Based Compensation

The Company has four Share-based payment plans and one restricted share award in place as at December 31, 2023:

- 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.

The contractual term is 10 years from grant date for options granted under the Plans. In general, each Company Option granted in 2023 has a four-year vesting period with 25% vesting after one year and the remaining 75% vesting in equal monthly installments over the next following three years.

Modification of Options

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 Company Options outstanding related to Ordinary Shares and their related weighted average exercise prices are as follows:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (in years)	Aggregate intrinsic value (in thousands 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 at December 31, 2024	7,884,500	$ 7.14	7.5	146,330

The weighted average grant date fair value of options, estimated as of the grant date using the Black-Scholes option pricing model, was $6.70, $4.70 and $4.32 per option for options granted during the years ended December 31, 2024, 2023 and 2022, respectively. The total intrinsic value (the amount by which the fair market value exceeded the exercise price) of stock options exercised during the years ended December 31, 2024 and 2023 was $27.2 million and $1.7 million, respectively. No stock options were exercised in 2022. Weighted average assumptions used to apply this pricing model were as follows:

	Year ended December 31,		
	2024	2023	2022
Expected life (years)	6.1	6.1	6.0
Risk-free rate	3.9%	4.1%	3.9%
Volatility	41.8%	38.1%	38.8%
Dividend yield	0.0%	0.0%	0.0%

Expected Term

The Company's expected term represents the period that the Company's stock-based awards are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term). The Company utilizes this method due to lack of historical exercise data and the plain-vanilla nature of the Company's stock-based awards.

Expected Volatility

Since the Company was privately held through November 2022, it alone does not have sufficient relevant company-specific historical data to support its expected volatility alone. In prior periods, due to the insufficiency of historical volatility data on the Company's own securities, the expected volatility input was determined using comparable companies alone. Beginning on January 1, 2024 expected volatility input was determined using a weighted average calculation considering the volatility of the Company's own securities and the volatilities of a representative group of publicly traded biopharmaceutical companies over a period equal to the expected term of the stock option grants. Initially, the volatility of the Company's Ordinary Shares is assigned a weighting of 10%. This weighting will be increased by 5% per calendar quarter (i.e. to 15% in Q2 2024, 20% in Q3 2024 and 25% in Q4 2024), until the expected volatility input is based entirely on the historical volatility of the Company's Ordinary Shares. For purposes of identifying comparable companies, the Company selected companies with comparable characteristics, including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards.

Risk-Free Interest Rate

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.

Expected Dividend

The expected dividend rate is zero as the Company currently has no history or expectation of declaring dividends on its ordinary shares.

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 Optionholders if and when a certain clinical development milestone is achieved during the earnout period. These Earnout Shares will be delivered in the form of awards of RSUs (the "Earnout RSUs") granted pursuant to the Plan to such Participating Optionholders who are, at the time of achievement of such milestone, still providing services to the Company.

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 in accordance with ASC 718.

The following summarizes the share-based payment expensed recognized by type of award and line-item:

(in thousands of USD)	Year ended December 31, 2024	2023	2022
Share-based compensation expense by type of award			
Share options	32,363	24,572	4,178
Restricted stock units	1,256	—	—
Total share-based compensation expense	33,619	24,572	4,178
Share-based compensation expense by line-item			
Research and development expenses	13,306	14,521	2,408
Selling, general and administrative expenses	20,313	10,051	1,770
Total share-based compensation expense	33,619	24,572	4,178

As of December 31, 2024, there was $27.1 million and $0.2 million of unrecognized compensation cost related to Company Options and Earnout RSUs that have not yet vested, respectively. These costs are expected to be recognized over a weighted average remaining vesting period of 2.9 years and 0.3 years for the Company Options and the Earnout RSUs, respectively.

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 installments over the following three years.

In connection with the award arrangement, if Dr. Davidson leaves the Company, all unvested Ordinary Shares will be cancelled against payment by the Company to him of the lower of the (i) the purchase price paid and (ii) the fair market value of such Ordinary Shares at the time of forfeiture. In order to reflect the consideration paid and the possibility that the Ordinary Shares would be repurchased if Dr. Davidson becomes a "Good Leaver" (as such term is defined in the award agreement) during the vesting period, the Company has recognized the consideration as a financial liability until the award has fully vested, at which time it will be reclassified to equity provided that Dr. Davidson remains with the Company. This liability is measured at the lower of (i) the purchase price paid and (ii) the fair market value of the Ordinary Shares at the end of the reporting period. The liability for unvested Ordinary Shares as at December 31, 2024 and 2023 amounted to nil and $0.1 million, respectively.

For the year ended December 31, 2024, the movements in the number of Ordinary Shares outstanding are as follows:

Outstanding as at December 31, 2023	608,779
Granted/purchased during the year	—
Outstanding as at December 31, 2024	608,779

As of December 31, 2024 and 2023, a total of 608,779 and 519,999 Ordinary Shares had vested, respectively.

Note 11. Segment Information

The Company has one operating segment and, therefore, one reportable segment, which comprises the discovery, development and commercialization of transformative therapies for cardio-metabolic diseases.

To date the Menarini License has been the only source of revenue to the Company and all such revenues derive from Italy. The nature of the revenues are described in detail in Note 4 - Revenue.

The chief operating decision maker assesses performance and decides how to allocate resources based on consolidated net loss and earnings/(loss) before tax, adjusted for certain non-cash and non-operating items such as share-based compensation, change in fair value of derivatives and foreign currency gains or losses. Adjusted

earnings/(loss) before taxes is used to monitor budget versus actuals and evaluate the operations of the Company. The measure of segment assets is reported on the balance sheet as total consolidated assets. The future prospects of the Company are highly dependent upon the results of its ongoing clinical trials and interactions with regulatory agencies. Such results and interactions are utilized together with assessment of the comparison of budget versus actuals in order to make decisions regarding the allocation of resources.

The following table presents the adjusted earnings/(loss) before taxes for the Company's single segment for each of the years ended December 31, 2024, 2023 and 2022:

	Year ended December 31,		
(In thousands of USD)	**2024**	**2023**	**2022**
Revenue	45,563	14,090	102,694
Interest income	16,881	11,283	—
Less:			
Personnel expense	33,391	14,475	7,067
External R&D expense	108,012	109,820	64,474
Manufacturing expense	17,188	27,430	15,852
Regulatory expense	2,186	1,297	878
Commercial programs	12,719	3,025	134
General and administrative expense	14,438	16,323	13,594
Depreciation and amortization	299	115	74
Interest expense	—	—	287
Segment adjusted loss before tax	(125,789)	(147,112)	334
Reconciliation to consolidated net loss			
Share-based compensation expense	(33,619)	(24,572)	(4,178)
Change in fair value - derivatives	(75,593)	(10,284)	(9,043)
Foreign exchange gains/(losses)	(6,598)	5,058	(9,747)
Income tax expense (benefit)	1	(27)	—
Consolidated net loss for the period	(241,598)	(176,937)	(22,634)

Note 12. Income Taxes

The Company’s breakdown of its income before provision for income taxes for the years ended December 31, 2024, 2023 and 2022 is as follows:

	Year ended December 31,		
(In thousands of USD)	**2024**	**2023**	**2022**
U.S.	(101,367)	(107,555)	(604)
Netherlands	(140,232)	(69,355)	(22,030)
Total	(241,599)	(176,910)	(22,634)

The components of our provision for income taxes for the years ended December 31, 2024, 2023 and 2022, are as follows:

(In thousands of USD)	Year ended December 31, 2024	2023	2022
Current:			
State	—	—	—
Federal	(1)	27	—
Total current	(1)	27	—
Deferred:			
State	—	—	—
Federal	—	—	—
Total deferred	—	—	—
Provision for income taxes	(1)	27	—

A reconciliation of the statutory federal income tax rate to our effective tax rate is as follows:

	Year ended December 31, 2024	2023	2022
Income tax at the federal statutory rate	25.80%	25.80%	25.80%
Foreign rate differential	(2.01%)	(2.94%)	(0.13%)
State taxes, net of federal benefit	1.30%	0.71%	(0.03%)
FDII deduction	—	—	0.24%
Warrants	—	(1.50%)	(1.19%)
162(m) Executive Compensation	(0.43%)	—	—
Tax credits	0.78%	5.31%	0.73%
Transaction costs	—	—	24.59%
Share listing expense	—	—	6.96%
Change in valuation allowance	(25.44%)	(27.40%)	(57.30%)
Other	—	—	0.33%
Effective tax rate	0.00%	(0.02%)	0.00%

Deferred income taxes reflect the tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets are as follows as of December 31, 2024 and 2023:

(In thousands of USD)	Year ended December 31, 2024	2023
Deferred tax assets:		
Amortization and depreciation	25,426	21,176
Accruals	135	509
Net operating loss carryforwards	133,595	75,686
Lease liability	109	13
IPR&D	22,884	22,884
Tax credit, federal	1,904	6,904
Tax credit, Massachusetts	685	2,685
Gross deferred tax assets	184,738	129,857
Valuation allowance	(184,633)	(129,845)
Deferred tax assets net of valuation allowance	105	12
Deferred tax liabilities:		
Right-of-use-asset	(105)	(12)
Net deferred tax assets	—	—

Realization of deferred tax assets is dependent on future taxable income, if any, the timing and the amount of which are uncertain. We assess the available positive and negative evidence to estimate whether sufficient future taxable income will be generated to permit use of the existing deferred tax assets. A significant component of objective negative evidence evaluated was our cumulative loss incurred over the three-year period ended December 31, 2024. Such objective evidence limits the ability to consider other subjective evidence, such as our projections for future

growth. On the basis of this evaluation, as at December 31, 2024, December 31, 2023 and December 31, 2022, a full valuation allowance has been recorded against our net deferred tax asset. As of December 31, 2024, and December 31, 2023, the Company had a valuation allowance of $184.6 million and $129.8 million, respectively, representing an increase of $54.8 million. The valuation allowance is recorded on the balance sheet. A valuation allowance is a non-cash charge, and does not limit the Company's ability to utilize its deferred tax assets, including its ability to utilize tax loss and credit carryforward amounts, against future taxable income. The amount of the deferred tax asset considered realizable, however, could be adjusted if estimates of future taxable income during the carryforward period are reduced or increased or if objective negative evidence in the form of cumulative losses is no longer present and additional weight is given to subjective evidence such as our projections for growth.

As of December 31, 2024, we had net operating loss carryforwards for Netherlands fiscal unity, US, and state income tax purposes of $420.3 million, $111.1 million, and $39.2 million, respectively. We also have federal research and development tax credit carryforwards of approximately $1.9 million that expire beginning in 2043 and state research and development tax credit carryforwards of approximately $0.7 million which can be carried forward indefinitely.

The future utilization of net operating loss and tax credit carryforwards and credits may be subject to an annual limitation, due to Dutch and US tax law and as a result of ownership changes that may have occurred previously or that could occur in the future. Due to the existence of the valuation allowance, limitations will not impact our effective tax rate.

We recognize a tax benefit from an uncertain tax position when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits. Income tax positions must meet a more likely than not recognition at the effective date to be recognized. As of December 31, 2024 we have not identified any unrecognized tax benefits that should be recorded.

We have elected to include interest and penalties as a component of tax expense. During the years ended December 31, 2024, 2023 and 2022, we did not recognize accrued interest and penalties related to unrecognized tax benefits. Although the timing and outcome of an income tax audit is highly uncertain, we do not anticipate that the amount of existing unrecognized tax benefits will significantly change during the next 12 months.

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.

We are subject to taxation in the United States, the Netherlands and various state jurisdictions. As of December 31, 2024, the tax years for 2021, 2022, and 2023 are subject to examination by the tax authorities in the United States and the tax year for 2023 is subject to examination by the tax authorities in the Netherlands. Due to our net operating loss and tax credit carryforwards, the income tax returns remain open to U.S. federal and state tax examinations. The Company is not currently under examination in any tax jurisdiction.

Note 13. Net Loss per Ordinary Share

As discussed in Note 3, in connection with the Business Combination the Participating Shareholders exchanged their interest in the outstanding shares of NewAmsterdam Pharma Holding B.V. for shares in the Company at a ratio of approximately 2.13. In order to present net loss per ordinary share on a comparable basis across all periods, the number of ordinary shares outstanding prior to the Business Combination have been adjusted for the exchange ratio of approximately 2.13 for the purposes of calculating the number of weighted average shares outstanding.

Basic and diluted net loss per ordinary share was calculated as follows:

(In thousands of USD, except share and per share amounts)	Year ended December 31, 2024	2023	2022
Net loss	(241,598)	(176,937)	(22,634)
Weighted average ordinary shares outstanding, basic and diluted	94,358,067	82,161,956	18,966,235
Net loss per ordinary share, basic and diluted	(2.56)	(2.15)	(1.19)

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average ordinary shares outstanding as they would be anti-dilutive:

	Year ended December 31, 2024	2023	2022
Stock options	19,029,056	15,783,509	11,146,861
Restricted Stock Units	143,002	—	—
Outstanding warrants	2,632,581	4,017,221	4,767,000
Total	21,804,639	19,800,730	15,913,861

Note 14. Benefit Plans

The Company sponsors a 401(k) retirement plan for its U.S. employees (the "US Plan") and a defined contribution pension plan for its employees in the Netherlands (the "NL Plan"). The US 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 $0.5 million, $0.1 million and $0.1 million for the years ended December 31, 2024, 2023 and 2022, respectively. Company contributions vest immediately for each participant.

Note 15. Commitments and Contingencies

Commitments

The Company has entered into a variety of agreements financial commitments in the normal course of business with contract research organizations, contract manufacturing organizations, 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-cancellable 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 $14.2 million.

According to the terms of the Menarini License the Company will be responsible for 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.

Note 16. 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.

Note 17. Subsequent Events

None.