
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 20-F/A
Amendment No. 1

(Mark One)

REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2022

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

OR

SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of event requiring this shell company report _____

Commission file number: 001-41562

NewAmsterdam Pharma Company N.V.
(Exact name of Registrant as specified in its charter)

The Netherlands
(Jurisdiction of incorporation)

Gooimeer 2-35
1411 DC Naarden
The Netherlands
(Address of principal executive offices)

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Gooimeer 2-35
1411 DC Naarden
The Netherlands
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be 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

Securities registered or to be registered pursuant to Section 12(g) of the Act: None**Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None**

Indicate the number of outstanding shares of each of the issuer's classes of capital stock or common stock as of the close of business covered by the annual report:

On December 31, 2022, the issuer had 81,559,780 ordinary shares, nominal value €0.12 per share, outstanding.

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

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. 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 preceding 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 (§232.405 of this chapter) 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 an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer Emerging growth company

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, 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 which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP

International Financial Reporting Standards as issued
by the International Accounting Standards Board

Other

If "Other" has been checked in response to the previous question indicate by check mark which financial statement item the registrant has elected to follow. Item 17 Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

EXPLANATORY NOTE

This amendment (the “Amendment”) to the annual report on Form 20-F of NewAmsterdam Pharma Company N.V. for the fiscal year ended December 31, 2022, filed on March 31, 2023 (the “Original Form 20-F”), is being filed for the purpose of restating the financial statements included in the Original Form 20-F under “Part III, Item 18 – Financial Statements” as further described below.

On October 18, 2024, the Audit Committee (the “Audit Committee”) of the Board of Directors of the Company (as defined below), after consultation with the Company’s management and independent registered public accounting firm, concluded that the Company’s previously issued consolidated financial statements as at December 31, 2022 and 2021 and for each of the three years in the period ended December 31, 2022 (the “Affected Financial Statements”), prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board and included in the Original Form 20-F, should no longer be relied upon due to certain errors in the calculation of the Company’s basic and diluted loss per share contained therein. The errors related to the reported weighted average ordinary shares outstanding for each period for which the Company’s consolidated statements for profit or loss and comprehensive loss are reported whereby the number of ordinary shares outstanding at the end of each period was erroneously reported as the weighted average number of ordinary shares outstanding, thus resulting in the erroneous reporting of the Company’s basic and diluted loss per share for each period presented in the Original Form 20-F.

Due to the discovery of this error, Company management reevaluated the effectiveness of the Company’s internal control over financial reporting as of December 31, 2022 and identified a material weakness in the Company’s internal control over financial reporting that existed as of December 31, 2022, relating to certain errors in the calculation of the Company’s basic and diluted loss per share presented in the Affected Financial Statements. The Amendment revises the risk factor titled “We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls 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” included in “Part I, Item 3 – Key Information – D. Risk Factors” to disclose the additional material weakness identified in connection with the error described above. The Amendment further revises the disclosure included in “Part II, Item 15 – Controls and Procedures – A. Disclosure Controls and Procedures” to include a discussion of the additional material weakness identified. The Amendment also revises “Part I, Item 6 – Directors, Senior Management and Employees – F. Disclosure of a Registrant’s Action to Recover Erroneously Awarded Compensation” to include a discussion of the Company’s conclusion with respect to the application of the Company’s Compensation Clawback Policy.

In accordance with Rule 12b-15 under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), the Amendment amends and restates in their entirety each item identified in the paragraph above. The Company is including with the Amendment new currently dated certifications of the Company’s Principal Executive Officer and Principal Financial Officer (attached as Exhibits 12.1, 12.1, 13.1 and 13.2).

Except as described above, this Amendment does not amend, update or change any other items or disclosures in the Original Form 20-F and does not purport to reflect any information or events subsequent to the filing thereof. As such, this Amendment reflects all information as of the date the Original Form 20-F was filed, and the Company has not undertaken herein to amend, supplement or update any information contained in the Original Form 20-F to give effect to any subsequent events. Accordingly, this Amendment should be read in conjunction with the Original Form 20-F and any subsequent filings by the Company with the SEC.

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MARKET AND INDUSTRY DATA

This Annual Report contains industry, market and competitive position data that are based on general and industry publications, surveys and studies conducted by third parties, some of which may not be publicly available, and our own internal estimates and research. Third-party publications, surveys and studies generally state that they have obtained information from sources believed to be reliable, but do not guarantee the accuracy and completeness of such information. These data involve a number of assumptions and limitations and contain projections and estimates of the future performance of the industries in which we operate that are subject to a high degree of uncertainty. We caution you not to give undue weight to such projections, assumptions and estimates.

GENERAL INFORMATION

Unless otherwise stated or the context otherwise indicates, (i) references to “we,” “our,” “us,” “Holdco” or the “Company” refer to NewAmsterdam Pharma Company N.V. (f/k/a NewAmsterdam Pharma Company B.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.

Our financial statements have been prepared in accordance with International Financial Reporting Standards (as issued by the International Accounting Standards Board (“IFRS”)) and our consolidated financial statements are presented in Euros. Unless otherwise indicated, all references in this Annual Report to “€,” “euro,” “EUR” or “cents” are to Euros. All references to “\$” are to U.S. dollars.

SERVICE MARKS AND TRADE NAMES

The NewAmsterdam Pharma name, logos and other service marks of NewAmsterdam Pharma appearing in this Annual Report are the property of NewAmsterdam Pharma. Solely for convenience, some of the service marks, logos and trade names referred to in this Annual Report are presented without the TM and SM symbols, but such references are not intended to indicate, in any way, that the Company will not assert, to the fullest extent under applicable law, its rights or the rights of the applicable licensors to these service marks and trade names. This Annual Report contains additional trademarks, service marks and trade names of others. All trademarks, service marks and trade names appearing in this Annual Report are, to the Company’s knowledge, the property of their respective owners. We do not intend the Company’s use or display of other companies’ trademarks, service marks, copyrights or trade names to imply a relationship with, or endorsement or sponsorship of the Company by, any other companies.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

- our public securities’ potential liquidity and trading;
- our ability to raise financing in the future;
- projected financial information, including assumptions about the efficacy of our product candidate, reimbursement and anticipated market size and market opportunity;
- our dependence on the success of our product candidate, obicetrapib, including obtaining of regulatory approval to market obicetrapib;
- our ability to attract and retain senior management and key scientific personnel;
- our limited experience in marketing or distributing products;
- managing the risks related to our international operations;
- our ability to achieve the broad degree of physician adoption and use and market acceptance necessary for commercial success;
- our reliance on third parties for all aspects of the manufacturing of obicetrapib for clinical trials; and
- our efforts to obtain, protect or enforce our patents and other intellectual property rights related to obicetrapib.

Forward-looking statements are subject to known and unknown risks and uncertainties and are based on potentially inaccurate assumptions that could cause actual results to differ materially from those expected or implied by the forward-looking statements. Accordingly, you should not rely on these forward-looking statements, which speak only as of the date of this Annual Report. We undertake 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 required by law. You should, however, review the factors and risks that we describe in the reports we file from time to time with the SEC.

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

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

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. [Reserved]

B. CAPITALIZATION AND INDEBTEDNESS

Not applicable.

C. REASONS FOR THE OFFER AND USE OF PROCEEDS

Not applicable.

D. RISK FACTORS

You should carefully consider the following risk factors, together with all of the other information included in this Annual Report, before making an investment in our ordinary shares, nominal value €0.12 per share (our "Ordinary Shares"). These risk factors are not exhaustive and investors are encouraged to perform their own investigation with respect to our business, financial condition and prospects. The occurrence of one or more of the events or circumstances described in these risk factors, alone or in combination with other events or circumstances, may have a material adverse effect on the business, cash flows, financial condition and results of operations of the Company. The risks discussed below may not prove to be exhaustive and are based on certain assumptions made by the Company which later may prove to be incorrect or incomplete. We may face additional risks and uncertainties that are not presently known to us, or that are currently deemed immaterial, which may also impair our business or financial condition.

You should carefully read and consider the matters discussed in this section of the Annual Report, which include the following risks:

- 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 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 never obtained approval for any product candidate, and may be unable to do so successfully.*
- Clinical drug development involves a lengthy and expensive process with uncertain outcomes, and 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.*

- *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.*
- *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 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 are eligible to be treated as an “emerging growth company,” and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make the Ordinary Shares less attractive to investors, which could have a material and adverse effect on the Company, including growth prospects, because we may rely on these reduced disclosure requirements.*
- *As a “foreign private issuer,” we are exempt from a number of rules under the U.S. securities laws and are permitted to file less information with the U.S. Securities and Exchange Commission (the “SEC”) than a U.S. domestic public company, which may limit the information available to holders of our Ordinary Shares and Warrants.*

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, including net losses of €28.6 million for the year ended December 31, 2021 and €78.1 million for the year ended December 31, 2022. 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;
- 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 cardio metabolic 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. At December 31, 2022, we had cash of €438.5 million, which we believe will be sufficient to fund our anticipated level of operations through 2026.

We will 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. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than would be desirable and we may be required to relinquish rights to some of our technologies, intellectual property or future product candidates or otherwise agree to terms unfavorable to us, any of which may harm our business, financial condition, operating results and prospects.

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.

While we believe that our existing cash will be sufficient to fund our operations through 2026, unless and until we can generate substantial product revenues, 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. 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.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect the Company's current and projected business operations and its financial condition and results of operations.

Actual events involving reduced or limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023 and March 12, 2023, Silicon Valley Bank, was closed by the California Department of Financial Protection and Innovation and Signature Bank was closed by New York state's Department of Financial Services, respectively, and in each case the Federal Deposit Insurance Corporation was appointed as receiver. Although we did not have any cash balances on deposit with either bank and are not a borrower or party to any agreement with either bank, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, or result in breaches of our financial and/or contractual obligations. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

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"), 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 FDIC insurance limit of \$250,000. 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 the FDIC insurance limitation, 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;
- our ability to implement strategies to minimize the impact of the COVID-19 pandemic 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;
- unless we have received a deferral or waiver, our ability to complete successfully any pediatric clinical trials agreed pursuant to the Pediatric Research Equity Act ("PREA") or its European Union ("EU") equivalent;
- that the Phase 3 clinical trials, even if successfully completed, will be sufficient to support a New Drug Application ("NDA") submission;
- the prevalence and severity of adverse events 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; and
- our ability to obtain, protect and enforce our intellectual property rights with respect to obicetrapib.

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 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.

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, and 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. 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 institutional review board (“IRB”) approval, or comparable ethics committee (“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; 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. 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, 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.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials, as applicable. 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, 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 of subjects in our clinical trials for obicetrapib. If we experience delays or difficulties enrolling 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 of subjects in future clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented. Trial costs have increased significantly following the COVID-19 pandemic and there may be delays in patient enrollment. 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 cardio metabolic diseases, and this competition will reduce the number and types of subjects available to us, because some subjects who might have opted to enroll in our trials may instead opt to enroll in a clinical trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of subjects who are available for our clinical trials at such clinical trial sites. Further, if patients are unwilling to enroll in our clinical trials because of the COVID-19 pandemic and restrictions on travel or healthcare institution policies or other impacts of the COVID-19 pandemic, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of our product candidate may be delayed.

Delays in subject enrollment 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 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 preliminary data we previously published. As a result, “topline” data should be viewed with caution until the final data are available.

Additionally, we 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 future preclinical testing and 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 Japan Pharmaceuticals and Medical Devices Agency in Japan (“PMDA”) and the China National Medical Products Administration in China (“NMPA”)) will accept the outcome of our preclinical testing and studies 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;
- 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.

Even if we eventually complete clinical testing and receive approval of any regulatory filing for obicetrapib, the FDA, the EMA or other comparable regulatory authorities (including the MHRA in the United Kingdom, the PMDA in Japan and the NMPA in China) may grant approval contingent on the performance of costly and potentially time-consuming additional post-approval clinical trials or subject to restrictive risk mitigation or surveillance requirements. 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 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. 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 are 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 cardiovascular outcomes trial (“CVOT”), in patients with atherosclerotic cardiovascular disease (“ASCVD”), and a Phase 2a clinical trial of obicetrapib in patients suffering from Alzheimer’s disease. The completion of this clinical trial or any of our other ongoing or future clinical studies may be delayed for a number of reasons, including:

- the FDA, EMA or any other regulatory authority may not agree to 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 studies;
- 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 cardio metabolic 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.

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 adverse events that can vary in severity and frequency. Side effects or adverse events 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 adverse events may negatively affect our ability to obtain regulatory approval or market obicetrapib. We cannot assure you that we will not observe drug-related serious adverse events 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 studies 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 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 that were not previously observed or reported.

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 adverse events. The timing of our obligation to report would be triggered by the date upon which we become aware of the adverse event as well as the nature and severity of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event 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 adverse events 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 U.S. and applicable foreign jurisdictions may be delayed, which could materially harm our business.

Our ongoing clinical trials are being undertaken 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 good clinical practice (“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 United States 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 global health concerns 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 agency 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 medical devices or modifications to be cleared or approved by government agencies, which would adversely affect our business. For example, 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.

Separately, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, in July 2020, the FDA resumed certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system, which it utilized to assist in determining when and where it was safest to conduct prioritized domestic inspections. In May 2021, the FDA outlined a detailed plan to move toward a more consistent state of inspectional operations, and in July 2021, the FDA resumed standard inspectional operations of domestic facilities and was continuing to maintain this level of operation as of September 2021. More recently, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns 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.

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, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration requirements and continued compliance with current good manufacturing practices ("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 adverse events 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.

Moreover, if obicetrapib is approved, our product labeling, advertising and promotion will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling.

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.

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 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, 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 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 cardio metabolic diseases with significant unmet medical needs. 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 or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. 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. 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 cardio metabolic 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 PCSK9 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 may advance its oral PCSK9 inhibitor, MK-0616, into phase 3 development. If approved, MK-0616 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, and in some cases, a single contractor, 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 manufacturers 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 also currently rely on a single supplier for our active ingredient and finished product for obicetrapib. While we believe that alternative sources of supply exist, 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.

We expect to continue to rely on these or other subcontractors and suppliers to support our commercial requirements if obicetrapib or any of our other product candidates 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 and for our clinical trials.

Our continuing reliance on third-party contract manufacturers 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 contract manufacturers 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 contract manufacturers 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 contract manufacturers 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.

The COVID-19 pandemic and government measures taken in response may also have an impact on our CROs, including due to travel or quarantine policies or prioritization of resources toward the pandemic, and any disruption in their performance would affect our ability to complete our clinical trials.

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 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 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 an exclusive License Agreement, dated June 23, 2022, with Menarini (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 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 a delay in the anticipated commercial launch, 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.

We do not have a sales or marketing infrastructure and 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 this Annual Report 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.

If in the future we acquire or in-license technologies or product candidates, we may incur various costs, may have integration difficulties as a result of becoming subject to onerous contractual requirements or restrictions, and may experience other risks that could harm our business and results of operations.

In the future, we may acquire or in-license additional product candidates and technologies. 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. If intellectual property related to product candidates or technologies we in-license is not adequate, we may not be able to commercialize the affected products even after expending resources on their development. 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.

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, 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. 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

The COVID-19 pandemic, and any future pandemics, may adversely affect our business and that of our suppliers, CROs or other third parties relevant to our business.

The COVID-19 pandemic has impacted worldwide economic activity and poses 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. We put in place a number of protective measures in response to the COVID-19 pandemic, which we reevaluate on a regular basis. Although restrictions imposed by governmental authorities have eased, if conditions worsen, we may need to implement new restrictive measures that could adversely affect our business. Further outbreaks and preventative or protective actions that governments, corporations or individuals may take in the future to contain the spread of COVID-19 may result in reduced operations, delays in the start of clinical trials or other research and

development efforts, business disruption for us and our suppliers, CROs and other third parties with which we do business, and potential delays or disruptions related to regulatory approvals.

Additionally, the COVID-19 pandemic has affected global economic conditions and resulted in significant financial market volatility and uncertainty. A continuation or worsening of the levels of market disruption and volatility seen in the past as a result of the COVID-19 outbreak could have an adverse effect on our ability to access capital and on the market price of our ordinary shares.

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

As of December 31, 2022, we had 17 full-time employees and nine 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. 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 financial resources and 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 we are found to have improperly promoted off-label use, or if physicians misuse our products, we may become subject to prohibitions on the sale or marketing of our product, significant sanctions and product liability claims, and our image and reputation within the industry and marketplace could be harmed.

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 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 cardio metabolic 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 Federal Food, Drug, and Cosmetic Act ("FDCA") and other statutory authorities, such as laws prohibiting false claims for reimbursement. The federal government 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 FDA 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.

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. 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, and our Chief Operating Officer, Douglas Kling. 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, 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. Moreover, we are domiciled and predominantly based in the Netherlands, which may make it difficult to hire necessary U.S.-based personnel.

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

We expect to experience 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 euro, in particular, the U.S. dollar. 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 euro. Therefore, for example, an increase in the value of the euro against the U.S. dollar could be expected to have a negative impact on our revenue and earnings growth as U.S. dollar revenue and earnings, if any, would be translated into euros 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, the COVID-19 pandemic and the war in Ukraine, may adversely impact our results of operations.

An unforeseen production shortage resulting from any events, including interruptions to business operations and supply chain disruption as a result of worldwide economic and political disruptions including the impacts of military conflict between Russia and Ukraine, and widespread health crises, such as the COVID-19 pandemic, 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 world 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 include, among others: expectations regarding our cash runway; estimates of the total addressable market for cardio metabolic 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. 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 impact of global health crises (including the COVID-19 pandemic), the imposition or heightening of sanctions or other economic or military measures in relation to the current Russia-Ukraine conflict, 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 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 that complement or augment our existing business. We may not be able to integrate any acquired business successfully or operate any acquired business profitably. Integrating any newly acquired business 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 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.

As part of our efforts to acquire companies, business or product candidates or to enter into other significant transactions, we 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. 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. 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, 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. If a disruption event were to occur and cause interruptions in our operations, 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.

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. As a result of the ongoing COVID-19 pandemic, 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.

We and certain of our service providers are from time to time subject to actual and attempted cyberattacks and security incidents. While we do not believe that we have experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our drug candidate and to conduct clinical trials, and similar events relating to their information technology systems could also have a material adverse effect on our business. To the extent that any disruption or security incident were to result 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 development and commercialization of our future drug candidates could be delayed. Similarly, if an actual or attempted security incident were to occur, in addition to reputational damage, we could face investigations and fines from regulators, as well as litigation.

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, contract manufacturers, 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 cardio metabolic disease or Alzheimer's disease 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 patent applications may not result in patents being issued which protect our technology or product candidates, effectively prevent others from commercializing competitive technologies and product 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 US 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 9 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. 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 abbreviated new drug application (“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 towards greater transparency and, while the manufacturing or quality information contained in an EU marketing authorization application ("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 study 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 Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, 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 Centers for Medicare & Medicaid Services (“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 Inflation Reduction Act (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, the U.S. Department of Health and Human Services ("HHS"), finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The IRA delayed the implementation of the rule to January 1, 2032. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers; the implementation of these provisions has also been delayed by the IRA until January 1, 2032. In addition, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate price cap, currently set at 100% of a drug's average manufacturer price for single source and innovator multiple source products, beginning on January 1, 2024. Further, in July 2021, the Biden Administration released an executive order that included multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug price reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions by HHS. No legislative or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of the budget reconciliation process. Additionally, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subjects drug manufacturers to civil monetary penalties and a potential excise tax for offering a price that is not equal to or less than the negotiated "maximum fair price" under the law, and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry. 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.

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 federal False Claims Act (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.

The federal Health Insurance Portability and Accountability Act of 1996 ("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 Centers for Medicare & Medicaid Services ("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. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry. We may also be subject to state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and/or state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidelines promulgated by the federal government.

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 General Data Protection Regulation 2016/679 ("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 are 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 be in compliance with these laws or 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 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 the U.S. Department of 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 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 foreign 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.

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, which 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.

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, 2022, we reported unused tax losses of €251.6 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 at 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, 2022) and that are still available for carry forward as of January 1, 2022 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 Act, 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 cannot guarantee, 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 its 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.

Our PFIC status could result in adverse U.S. federal income tax consequences to U.S. Holders.

We believe the Company and its non-U.S. subsidiaries, including NewAmsterdam Pharma, will be treated as passive foreign investment companies (each, a "PFIC") for U.S. federal income tax purposes for the taxable year during which the Business Combination was completed and may be treated as PFICs for future taxable years. A non-U.S. corporation is classified as a PFIC for any tax year if at least 75% of its gross income is "passive income" or at least 50% of the value of its assets, determined on the basis of quarterly averages, is attributable to assets that produce or are held for the production of "passive income."

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 Frazier Lifesciences Acquisition Corporation ("FLAC").

Based on the composition of the income and assets of the Company and its subsidiaries, it is expected that NewAmsterdam Pharma, the Company and other non-U.S. subsidiaries will be PFICs for the 2022 taxable year and may be PFICs for future taxable years. 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.

A U.S. Holder (as defined in this Annual Report in the section entitled "*Material Tax Considerations—Material U.S. Federal Income Tax Considerations*") generally will be subject to additional U.S. federal income taxes and interest charges on the gain from a sale of Ordinary Shares or the public warrants issued in connection with FLAC's initial public offering (the "Public Warrants," and together with the warrants acquired by the Frazier Lifesciences Sponsor LLC (the "Sponsor") in a private placement (the "Private Placement Warrants") in connection with FLAC's initial public offering, the "Warrants") and on receipt of an "excess distribution" with respect to Ordinary Shares or any of its non-U.S. subsidiaries. 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.

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) (the “Resale Registration Statement”) registering up to 77,092,642 Ordinary Shares (the “Resale Shares”) for resale by certain of our securityholders. The Resale Shares represent approximately 89.3% of our issued and outstanding Ordinary Shares as of December 31, 2022 (assuming the exercise of the Warrants), consisting of (i) up to 23,460,000 PIPE Shares, (ii) up to 48,865,642 IRA Shares, (iii) up to 167,000 Ordinary Shares that are issuable upon the exercise of the Private Placement Warrants and (iv) up to 4,600,000 Ordinary Shares that are issuable upon the exercise of the Public Warrants. The securities being offered for resale pursuant to the Resale Registration Statement 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 our board of directors (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 “*Item 10. Additional Information—B. Memorandum and Articles of Association.*”

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

The stock markets, including The Nasdaq Stock Market LLC (“Nasdaq”) on which we have listed the Ordinary Shares and 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 this Annual Report;
- additions and departures of key personnel;
- failure to comply with the requirements of Nasdaq;
- failure to comply with the Sarbanes-Oxley Act 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 government closure of Silicon Valley Bank and liquidity concerns at other 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 (including the ongoing COVID-19 pandemic), 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 The Nasdaq Global Market under the symbol “NAMS” and our Public Warrants are traded on The Nasdaq Global Market under the symbol “NAMS.W.” 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. As a new public company, we may be slow to attract research coverage and the analysts who publish information about the Ordinary

Shares will have had relatively little experience with the Company, which could affect their ability to accurately forecast our results and make it more likely that we fail to meet their estimates. In the event we obtain industry or financial analyst coverage, 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 or no 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. Such conversion imposes additional burdens on our management team.

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 and, as such, Dutch private international law governs the rights of our shareholders and the civil liability of our directors and executive officers are governed in certain respects by the laws of the Netherlands. The ability of our shareholders in certain countries other than the Netherlands to bring an action against us or our directors and executive officers may be limited under applicable law. In addition, substantially all of our assets are located outside the United States. As a result, it may not be possible for shareholders to effect service of process within the United States upon us or our directors and executive officers or to enforce judgments against them in U.S. courts, including judgments predicated upon the civil liability provisions of the federal securities laws of the United States. In addition, it is not clear whether a Dutch court would impose civil liability on us or our directors and executive officers in an original action based solely upon the federal securities laws of the United States brought in a court of competent jurisdiction in the Netherlands.

As of the date of this Annual Report, there is no treaty in effect between the United States and the Netherlands providing for the reciprocal recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters. It is noted that, on the date of this Annual Report, the Hague Convention on Choice of Court Agreements of June 30, 2005, has entered into force for the Netherlands, but has not entered into force for the United States. The Hague Convention of July 2, 2019 on the Recognition and Enforcement of Foreign Judgments in Civil or Commercial Matters has not entered into force for either the Netherlands or the United States. Accordingly, a judgment rendered by a court in the United States, whether or not predicated solely upon U.S. securities laws, would 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 such judgment if (i) the jurisdiction of the U.S. court was based on a ground of jurisdiction that is generally acceptable according to international standards, (ii) the judgment by the U.S. 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 U.S. judgment is not contrary to Dutch public order (*openbare orde*) and (iv) the judgment by the U.S. 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 U.S. judgment is given binding effect, a claim based thereon may, however, still be rejected if the U.S. judgment is not or no longer formally enforceable. Dutch courts may deny the recognition and enforcement of punitive damages or other awards. Moreover, a Dutch court may reduce the amount of damages granted by a U.S. court and recognize damages only to the extent that they are necessary to compensate actual losses or damages. Enforcement and recognition of judgments of U.S. courts in the Netherlands are solely governed by the provisions of the Dutch Code of Civil Procedure (*Wetboek van Burgerlijke Rechtsvordering*).

Based on the lack of a treaty as described above, U.S. investors may not be able to enforce against us or our directors, representatives or certain experts named herein who are residents of the Netherlands or countries other than the United States, any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

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 us 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.

Each of the Sponsor and NewAmsterdam Pharma's former shareholders own a significant portion of Ordinary Shares and have representation on the Board of Directors. The Sponsor and NewAmsterdam Pharma's former shareholders may have interests that differ from those of other shareholders.

As of December 31, 2022, approximately 16.2% of our Ordinary Shares were owned by the Sponsor and the former holders of all other issued and outstanding FLAC Class B ordinary shares (together, the "FLAC Shareholders"), approximately 44.5% were owned by NewAmsterdam Pharma's former shareholders (excluding Ordinary Shares purchased in the PIPE Financing) and approximately 23.2% of our Ordinary Shares were owned by the PIPE Investors (as defined below) (excluding the FLAC

Shareholders and affiliates of the Sponsor). These levels of ownership interests assume that (i) none of the Warrants have been exercised, (ii) none of the 1,886,137 Earnout Shares (as defined below) have been issued, and (iii) no options to purchase Ordinary Shares (the “Options”) or awards that may be issued under the Company’s long-term incentive plan have been exercised. In addition, two of our non-executive director nominees were designated by FLAC. As a result, the Sponsor and NewAmsterdam Pharma’s former 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 the Sponsor or its affiliates and certain of our current 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. Additionally, the Sponsor, which is in the business of making investments in companies and which may from time to time acquire and hold interests in businesses that compete directly or indirectly with us or that supply us with goods and services. The Sponsor may also pursue acquisition opportunities that may be complementary to (or competitive with) our business, and as a result those acquisition opportunities may not be available to us. Investors in our Ordinary Shares should consider that the interests of the Sponsor or its affiliates and certain of our current 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 IFRS. As a result of becoming a public company, we are required, pursuant to the Sarbanes-Oxley Act, 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 the Sarbanes-Oxley Act. We could be an “emerging growth company” for up to five years. 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. We are in the very early stages of the costly and challenging process of planning the activities necessary to perform the evaluation needed to comply with Section 404.

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. If we are unable to remediate these material weaknesses, identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls 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, 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, among which a sufficient level of management review and approval, manual processes, roles and responsibilities, and adequate application and controls over information technology; and
- failure to maintain a sufficient complement of personnel commensurate with its accounting and reporting requirements as it continues to grow as a company, and ability to: (i) design and maintain formal accounting policies, procedures and controls over the fair presentation of financial statements; (ii) analyze, record and disclose complex accounting matters timely and accurately; and (iii) design and maintain controls over the preparation and review of journal entries and financial statements, including maintaining appropriate segregation of duties.

In addition, subsequent to the filing of the Original Form 20-F, management identified an additional material weakness relating to certain errors in the calculation of the Company's basic and diluted loss per share presented in the Affected Financial Statements filed as part of the Original Form 20-F. As discussed in the Explanatory Note to this Amendment, the error related specifically to the inaccurate reporting of weighted average ordinary shares outstanding for the purpose of calculating earnings per share, which resulted in an inaccurate presentation of the Company's basic and diluted loss per share for each of the periods presented in the Affected Financial Statements. This material weakness resulted from a lack of sufficient review of our financial statements, including review to determine the accuracy and completeness of our earnings per share calculations, and resulted in a restatement of the Affected Financial Statements.

We have taken steps to develop a remediation plan designed to address the material weaknesses described above and expect to take additional steps to fully remediate our material weaknesses. The company was a small private company with a limited number of employees and did not have a formal documented controls framework before it became a listed entity in November 2022. As a public emerging growth company, significant investments need to be made in our accounting, finance and controlling capabilities and we need to develop and implement a risk and internal controls framework that will allow the company to address the material weaknesses, effectively manage our strategic, operational and financial risks and ultimately meet Sarbanes-Oxley Act of 2002 requirements. Management has developed a plan and secured resources, which include external advisors and specialists, and will execute this plan under the guidance, supervision and oversight of the Audit Committee, to achieve the objective of remediating the material weaknesses and having an effective internal controls framework. Our planned remediation efforts include, but are not limited to:

- investing in and continuing to hire additional finance, accounting and IT resources with appropriate knowledge and expertise to effectively operate financial reporting processes and internal controls, including conducting a search for a new Chief Financial Officer and the use of third-party consultants and specialists;
- designing and implementing controls to formalize roles and review responsibilities to align with our team's skills and experience, including over segregation of duties and information technology solutions;
- internalizing our business processes and accounting systems by implementing a new ERP system in February 2023 to develop, automate and enhance our internal control over financial reporting, including controls designed to ensure the accurate calculation of reported earnings per share; and
- implementing a comprehensive and continuous risk assessment process to identify and assess risks of material misstatement.

The material weaknesses described above resulted in a material misstatement that was corrected in our consolidated financial statements. In addition, as described above, the material weakness related to the error regarding calculation of the Company's basic and diluted loss per share resulted in the restatement of the Affected Financial Statements. The material weaknesses described above could result in additional misstatements of one or more account balances or disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected. As a result of the material weaknesses in our internal controls over financial reporting, our management has concluded that as of December 31, 2022, our disclosure controls and procedures were not effective.

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 remediate the control deficiencies that led to these material weaknesses in our internal control over financial reporting or that they will prevent or avoid potential future material weaknesses. If we are unable to successfully remediate our material weaknesses, or identify any 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.

In addition, neither our management nor an independent registered public accounting firm has performed an evaluation of our internal control over financial reporting in accordance with the provisions of Section 404 of the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley Act. Had we or our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional material weaknesses may have been identified.

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 the Sponsor or their 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 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, 2022, Warrants to purchase an aggregate of 4,767,000 Ordinary Shares were outstanding and are exercisable in accordance with the terms of the Warrant Assumption Agreement. The Warrants became exercisable on December 22, 2022, 30 days after the completion of the Business Combination. 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 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, 2022, there were 11,146,861 shares issuable upon the exercise of options granted under the LTIP, Rollover Plan and Supplementary LTIP (each as defined below) at a weighted

average exercise price of \$6.71. 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 five years from the day following the Closing Date, November 23, 2022, 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.

Future issuances of equity securities may adversely affect us, including the market price of our Ordinary Shares, and may be dilutive to existing shareholders.

In the future, we may issue equity ranking senior to our Ordinary Shares. Such securities will generally have priority upon liquidation and may be governed by an instrument containing covenants restricting our operating flexibility. Additionally, any convertible or exchangeable securities that we issue in the future may have rights, preferences and privileges more favorable than those of our Ordinary Shares. Because our decision to issue equity in the future will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing, nature or success of our future capital raising efforts. As a result, future capital raising efforts may reduce the market price of our Ordinary Shares and be dilutive to existing shareholders.

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 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 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 staggered multi-year terms of our directors, as a result of which only part of our 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 a "foreign private issuer," we are exempt from a number of rules under the U.S. securities laws and are permitted to file less information with the U.S. Securities and Exchange Commission (the "SEC") than a U.S. domestic public company, which may limit the information available to holders of our Ordinary Shares and Warrants.

We are a "foreign private issuer," as such term is defined in Rule 405 under the Securities Act. Because we qualify as a "foreign private issuer" under the Exchange Act, we are exempt from certain provisions of the Exchange Act that are applicable to U.S.

domestic public companies, including (1) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act, (2) the sections of the Exchange Act requiring insiders to file public reports of their share ownership and trading activities and liability for insiders who profit from trades made in a short period of time and (3) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, although we are subject to Dutch laws and regulations with regard to certain of these matters and intend to furnish certain quarterly information on Form 6-K. In addition, foreign private issuers are not required to file their annual report on Form 20-F until 120 days after the end of each fiscal year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year and U.S. domestic issuers that are large accelerated filers are required to file their annual report on Form 10-K within 60 days after the end of each fiscal year. As long as we are eligible for the foreign private issuer exemption, we will not be required to obtain shareholder approval for certain dilutive events, such as the establishment or material amendment of certain equity-based compensation plans, we will not be required to provide detailed executive compensation disclosure in our periodic reports, and we will be exempt from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We may lose foreign private issuer status in the future, which could result in significant additional costs and expenses.

As discussed above, we are a “foreign private issuer,” and therefore are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act. The determination of foreign private issuer status is made annually on the last business day of an issuer’s most recently completed second fiscal quarter, and, accordingly, the next determination will be made with respect to the Company on June 30, 2023. In the future, we would lose our foreign private issuer status if more than 50% of our outstanding voting securities are owned by U.S. residents and any of the following three circumstances applies: (i) the majority of our executive officers or directors are U.S. citizens or residents, (ii) more than 50% of our assets are located in the United States or (iii) our business is administered principally in the United States. If we lose our foreign private issuer status, we will be required to file with the SEC periodic reports and registration statements on U.S. domestic issuer forms, which are more detailed and extensive than the forms available to a foreign private issuer. We would have to begin preparing our financial statements in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”) which are different than our historical financial statements and may make it difficult for investors to compare our financial performance over time. We would also have to mandatorily comply with U.S. federal proxy requirements, and our officers, directors and principal shareholders will become subject to the short-swing profit disclosure and recovery provisions of Section 16 of the Exchange Act. In addition, we would lose our ability to rely upon exemptions from certain corporate governance requirements under the listing rules of Nasdaq. As a U.S. listed public company that is not a foreign private issuer, we would incur significant additional legal, accounting and other expenses that we will not incur as a foreign private issuer.

As we are a “foreign private issuer” and follow certain home country corporate governance practices, our shareholders may not have the same protections afforded to shareholders of companies that are subject to all Nasdaq corporate governance requirements.

As a “foreign private issuer,” we have the option to follow certain home country corporate governance practices rather than those of Nasdaq, provided that we disclose the requirements we are not following and describes the home country practices we are following. As a result, in accordance with the listing requirements of Nasdaq we rely on home country governance requirements and certain exemptions thereunder rather than relying on the corporate governance requirements of Nasdaq. In accordance with Dutch law and generally accepted business practices, our Articles of Association do not provide quorum requirements generally applicable to general meetings. To this extent, our practice varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting shares. Although we must provide shareholders with an agenda and other relevant documents for our General Meetings, Dutch law does not have a regulatory regime for the solicitation of proxies and the solicitation of proxies is not a generally accepted business practice in the Netherlands, thus our practice will vary from the requirement of Nasdaq Listing Rule 5620(b). As permitted by the listing requirements of Nasdaq, we have also opted out of the requirements of Nasdaq Listing Rule 5605(b)(2), which requires that independent directors have regularly scheduled meetings at which only independent directors are present. In addition, we have opted out of shareholder approval requirements, as included in the Nasdaq Listing Rules, for the issuance of securities in connection with certain events such as the acquisition of shares or assets of another company (if, due to the potential issuance of ordinary shares, the ordinary shares would have upon issuance voting power equal to or in excess of 20% of the voting power outstanding before the issuance of stock), the establishment of or amendments to equity-based compensation plans for employees, a change of control of our

company and certain private placements. To this extent, our practice varies from the requirements of Nasdaq Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events. Accordingly, you may not have the same protections afforded to shareholders of companies that are subject to these Nasdaq requirements.

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 centre 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 under U.S. insolvency laws.

We are eligible to be treated as an “emerging growth company,” and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make the Ordinary Shares less attractive to investors, which could have a material and adverse effect on us, including growth prospects, because we may rely on these reduced disclosure requirements.

We qualify as an emerging growth company within the meaning of the Securities Act, and if we takes advantage of certain exemptions from disclosure requirements available to emerging growth companies, it could make our securities less attractive to investors and may make it more difficult to compare our performance with other public companies.

We are eligible to be treated as an emerging growth company, as defined in Section 2(a) of the Securities Act, as modified by the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised financial accounting standards until such time as those standards apply to private companies. If we no longer qualify as a “foreign private issuer,” we intend to take advantage of this extended transition period under the JOBS Act for adopting new or revised financial accounting standards.

We will remain an “emerging growth company” until the earliest to occur of (i) the last day of the fiscal year (a) following the fifth anniversary of the effective date of the registration statement on Form F-4, filed by the Company in connection with the Business Combination, (b) in which we have total annual gross revenue of at least \$1.235 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of the Ordinary Shares that is held by non-affiliates exceeds \$700 million as of the last business day of our prior second fiscal quarter, and (ii) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

For as long as we continue to be an emerging growth company, it may also take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including presenting only limited selected financial data, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, and to the extent we no longer qualified as a “foreign private issuer,” reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. As a result, our shareholders may not have access to certain information that they may deem important.

We cannot predict if investors will find Ordinary Shares less attractive because we may rely on these exemptions. If some investors find the Ordinary Shares less attractive as a result, there may be a less active trading market for Ordinary Shares and the price of Ordinary Shares may be more volatile. Further, there is no guarantee that the exemptions available to us under the JOBS Act will result in significant savings. To the extent that we choose not to use exemptions from various reporting requirements under the JOBS Act, it will incur additional compliance costs, which may impact our financial condition.

ITEM 4. INFORMATION ON THE COMPANY

A. HISTORY AND DEVELOPMENT OF THE COMPANY

Our legal and commercial name is NewAmsterdam Pharma Company N.V. We were incorporated as a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) under the laws of the Netherlands on June 10, 2022, solely for the purpose of effectuating the Business Combination. As part of the Business Combination, we converted our legal form to a public limited liability company (*naamloze vennootschap*) under the laws of the Netherlands on November 21, 2022. The Company is registered with the Dutch Trade Register under number 86649051. The address of our registered office is Gooimeer 2-35 1411 DC Naarden, the Netherlands and the telephone number of the Company is +31 (0) 35 206 2971. Our agent in the United States is our subsidiary, NewAmsterdam Pharma Corporation. NewAmsterdam Pharma Corporation's address is 20803 Biscayne Blvd, Suite #105, Aventura, Florida.

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

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

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

Upon the achievement of a certain clinical development milestone, we will issue to the Participating Shareholders (including Saga Investments Coöperatief U.A. (“Amgen”), an affiliate of Amgen, Inc., and Mitsubishi Tanabe Pharma Corporation (“MTPC”) for this purpose) and holders of options to purchase shares of NewAmsterdam Pharma prior to the closing of the Business Combination, who were directors, officers, employees or consultants of NewAmsterdam Pharma as of the date of the Business Combination Agreement and who are at the time of achievement of such milestone providing services to the Company or its subsidiaries (the “Participating Optionholders”), 1,886,137 additional Ordinary Shares (the “Earnout Shares”), which in the case of the Participating Optionholders will take the form of awards of restricted stock units under the LTIP. Of the total Earnout Shares 1,725,358 Earnout Shares and 160,778 Earnout Shares are currently allocated to Participating Shareholders and Participating Optionholders, respectively. The development milestone consists of the achievement and public announcement of Positive Phase 3 Data (as defined in the Business Combination Agreement) for each of NewAmsterdam Pharma’s BROADWAY clinical trial and BROOKLYN clinical trial at any time during the period beginning on the date immediately prior to the Closing Date and ending on the date that is five years after the date immediately after the Closing Date, or November 23, 2027. As a result, no Earnout Shares will be issuable if the applicable milestone is not achieved within five years of the Merger.

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

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

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

Our principal capital expenditures for the years ended December 31, 2022, 2021, and 2020 amounted to €13 thousand, €192 thousand and €13 thousand, respectively. These capital expenditures primarily relate to the purchase of computers and office equipment, and right of use for office space.

B. BUSINESS OVERVIEW

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

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

A significant proportion of patients with high cholesterol do not achieve acceptable LDL-C levels using statins alone. We estimate that there are more than 35 million patients in the United Kingdom, Germany, France, Spain and Italy (collectively, “EU5”) and in the United States who are not achieving LDL-lowering goals on the current standard of care. Existing non-statin treatment options have been largely unable to address the needs of patients with high cholesterol due to modest efficacy, prohibitive pricing, or

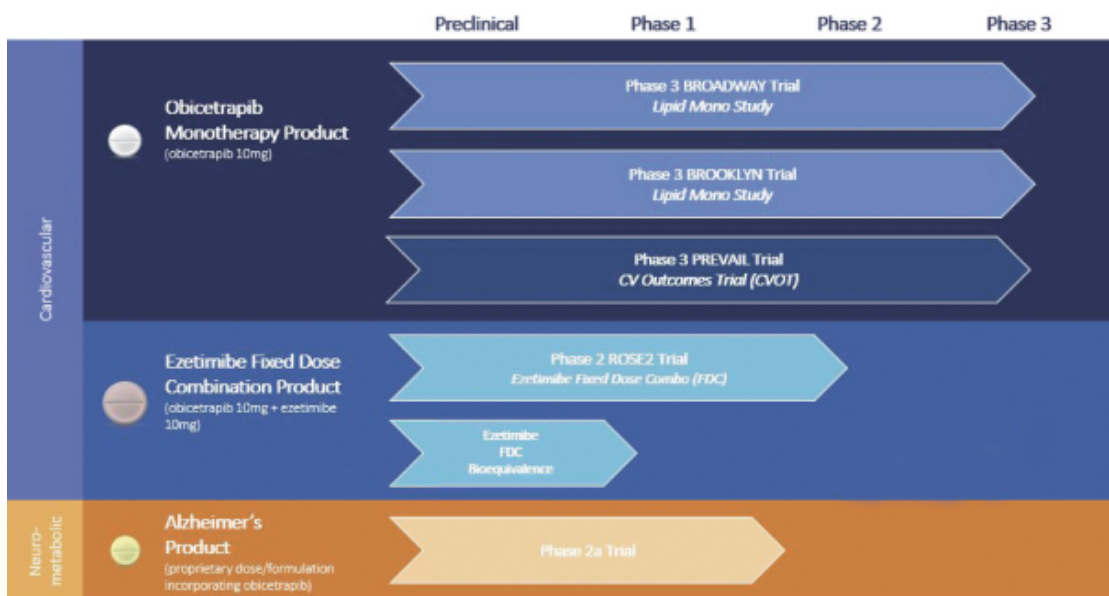
an inconvenient and painful injectable administration route. It is estimated that over 75% of ASCVD outpatients prefer oral drugs to injectable therapies.

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

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

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

The following table summarizes our current clinical programs:



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

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

We are also investigating obicetrapib as a fixed dose combination with ezetimibe, a non-statin oral LDL-lowering therapy, and plan to seek approval for this fixed dose combination in parallel with obicetrapib monotherapy. In our Phase 2b ROSE2 trial, we are evaluating the efficacy and safety of obicetrapib plus ezetimibe compared to obicetrapib and placebo alone. A fixed dose combination tablet will be evaluated in two bioequivalence studies, a pilot bioequivalence study and a potentially pivotal bioequivalence study. In the pilot bioequivalence study, which we commenced in September 2022, the bioavailability of two fixed dose combination formulations are being compared to the concomitant administration of obicetrapib and ezetimibe. After the pilot bioequivalence study, which we expect to complete in the second half of 2023, one final fixed dose combination formulation will be selected for a potentially pivotal bioequivalence study, to evaluate whether the fixed dose combination is bioequivalent to the concomitant administration of obicetrapib and ezetimibe. In parallel to the potentially pivotal bioequivalence study, a 12-week, phase 3 efficacy and safety study will be conducted with the fixed dose combination. This study will compare the safety and efficacy of the fixed dose combination compared to placebo, obicetrapib and ezetimibe. We expect that both the potentially pivotal bioequivalence study and the phase 3 efficacy and safety study, along with the PREVAIL CVOT study, will be described in the fixed dose combination product label, if approved.

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

Our Management Team and Investors

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

Kling, our Chief Operating Officer, is an expert in the development of drugs to treat dyslipidemia and CVD, and has managed clinical operations at both Corvidia Therapeutics, Inc. and Omthera Pharmaceuticals, Inc.

In addition, we are backed by leading life sciences investors, including Forbion and Morningside Ventures. Prospective investors should not rely on the past investment decisions of our investors, as our investors may have different risk tolerances and may have received their shares in prior offerings at a significant discount to the market price. See “Item 5. Operating and Financial Review and Prospects—B. Liquidity and Capital Resources—Sources of Liquidity” for more information.

Cardiovascular Disease and Hyperlipidemia

Market Overview

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

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

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

Unmet Medical Need

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

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

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

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

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

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

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

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

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

contributes to atherosclerosis. However, unlike statins, based on observations from our Phase 2 clinical trials, obicetrapib also decreases the presence of lipoprotein(a) (“Lp(a)”), an important biomarker for CVD risk reduction.

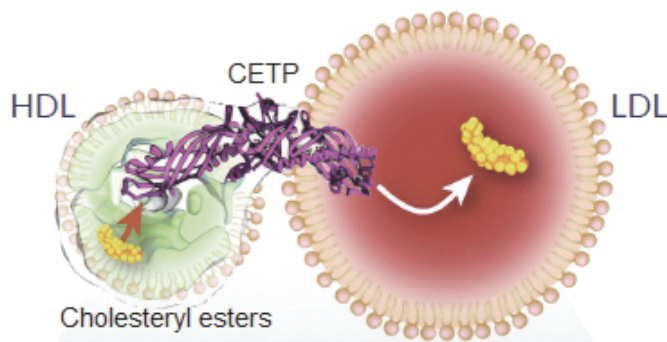
Lowering LDL-C Through CETP Inhibition

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

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

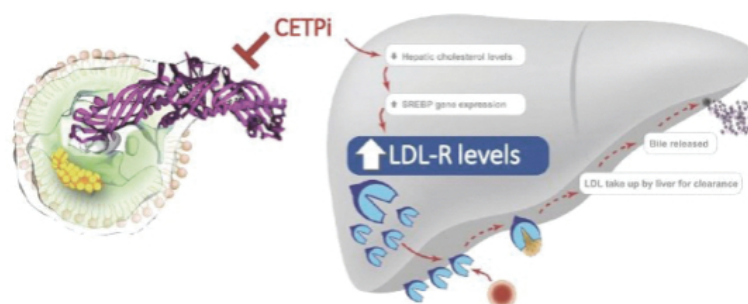
CETP is a plasma glycoprotein produced in the liver that circulates in the blood primarily bound to a high-density lipoprotein cholesterol (“HDL-C” or “HDL”) particle which can also attach to an LDL particle and form a bridge to transfer cholesterol from HDL to LDL, as shown in the figure below. CETP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

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



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

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



Limitations of Current Non-Statin Therapies

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

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

- Ezetimibe. Non-statin cholesterol-lowering medications, such as ezetimibe, function by preventing the absorption of cholesterol in the intestines by blocking the NPC1L1 protein. Although these drugs are administered at a low dose, which contributes to their safety and tolerability, and are generic and broadly available, they have been shown to only moderately reduce LDL-C. Ezetimibe has been observed to reduce LDL-C by approximately 25% compared to baseline. We believe this relatively modest efficacy supports why relatively few patients and prescribers prefer to utilize these medications.
- Nexletol/Nexlizet. The other currently available oral non-statin, Nexletol/Nexlizet, which also inhibits an enzyme involved in cholesterol synthesis, shows only modest improvement in lowering LDL-C. Nexletol/Nexlizet has been observed to reduce LDL-C by approximately 15% compared to baseline. Along with its relatively modest efficacy, Nexletol/Nexlizet's label contains safety warnings that include tendon rupture and gout. Given that Nexletol/Nexlizet's efficacy profile is comparable to generic ezetimibe, payors are reluctant to cover its branded price, thus limiting its access.
- PCSK9 Inhibitors. The PCSK9 inhibitors on the market are injectable, monoclonal antibodies and small interfering RNA that have been observed to reduce LDL-C levels by approximately 50% compared to baseline. While PCSK9 inhibitors have demonstrated their effectiveness at reducing LDL-C when used alone and as an adjunct to statin therapy, we believe their injectable route of administration makes them inconvenient for patients, and their access is further limited by their associated high cost and low rates of prescription approval by payors. It is estimated that over 75% of ASCVD outpatients prefer oral drugs to injectable therapies.

Limitations of Prior Attempts to Develop CETP Inhibitors

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

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

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

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

In a Phase 3 REVEAL CVOT with approximately 30,000 patients with ASCVD receiving intensive atorvastatin therapy, for anacetrapib, its MACE benefits were observed to be predicted by the magnitude of the LDL-C reduction, suggesting that CETP inhibitors behave like statins in reducing MACE. The REVEAL trial began enrollment in August 2011 and completed its long-term follow-up in April 2019. A median four-year follow-up of the REVEAL trial showed that CETP inhibition resulted in a nine percent reduction in MACE (first major coronary event, a composite of coronary death, myocardial infarction or coronary revascularization) compared to placebo. We believe the REVEAL results provide clinical support showing that the absolute reduction in LDL-C over time by CETP inhibition confers a predictable benefit in the prevalence of adverse cardiovascular outcomes, as measured by MACE. However, due to a very low baseline level of LDL-C (61 mg/dl), the trial showed only a modest absolute LDL-C lowering of 11 mg/dl (17%). In addition, anacetrapib's commercial viability was limited by its lipophilicity, which caused it to accumulate in fat tissue over time.

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

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

Our Strategy

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

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

- **Advance the clinical development of obicetrapib as a next-generation oral, low-dose, once-daily LDL-lowering treatment as a monotherapy and a combination therapy with ezetimibe.** We are conducting two Phase 3 pivotal trials: BROADWAY, which began enrolling patients in January 2022, and BROOKLYN, which began enrolling patients in July 2022, to evaluate obicetrapib as a monotherapy used as an adjunct to maximally tolerated lipid-lowering therapies to potentially enhance LDL-lowering for high-risk CVD patients. We also commenced our Phase 3 PREVAIL CVOT in March 2022, designed to assess obicetrapib's potential to reduce occurrences of MACE, including cardiovascular death, non-fatal myocardial infarction, non-fatal stroke and non-elective coronary revascularization, and a Phase 2b trial, ROSE2, to investigate obicetrapib as a fixed dose combination with ezetimibe. We are also conducting a Phase 2 dose-finding study of obicetrapib as an adjunct to stable statin therapy in patients with dyslipidemia in Japan. We expect to report data from our Phase 3 BROADWAY trial and our Phase 3 BROOKLYN trial in 2024. We expect to report data from our Phase 3 PREVAIL CVOT in 2026. We also expect to report data from our Phase 2 dose-finding study of obicetrapib as an adjunct to stable statin therapy in patients with dyslipidemia in Japan in the second half of 2023.
- **Obtain marketing approval from regulatory agencies.** We currently plan to seek approval of obicetrapib in the United States, the EU, Japan, China and the United Kingdom. We are executing multiple Phase 3 trials simultaneously, with clinical plans that incorporate feedback from the FDA, EMA, PMDA and NMPA. We have also initiated a Phase 2 study specifically in Japan and are including sufficient numbers of patients in Japan to support approval in those markets on the same timelines as the U.S. and Europe.
- **Commercialize obicetrapib for the treatment of cardiometabolic disease.** We are focused on selecting optimal partners in targeted geographies at the right time in obicetrapib's development and commercialization process. If we obtain marketing approval, both independently and, in certain jurisdictions through collaborations, we intend to commercialize obicetrapib for patients suffering from cardiometabolic disease. We have partnered with Menarini to exclusively commercialize obicetrapib 10 mg either as a sole active ingredient product or in a fixed dose combination with ezetimibe in the majority of European countries, if approved. Subject to receipt of marketing approval, our current plan is to pursue development and commercialization of obicetrapib in the United States ourselves, and to consider additional partners for jurisdictions outside of the United States and the EU, including in Japan, China and the United Kingdom.
- **Continue advancing the clinical development of obicetrapib for the treatment of Alzheimer's disease.** Evidence observed in our preclinical studies suggests that cholesterol accumulation in the brain may be a precursor to Alzheimer's disease. For example, rodents lack the CETP gene and are resistant to Alzheimer's disease. In early preclinical studies, when the human CETP gene was knocked into a mouse, the cholesterol content of the mouse brain was observed to increase by 25% and when combined with the gene for the amyloid precursor protein, hypothesized to be a driver of Alzheimer's disease, the risk of developing Alzheimer's disease may greatly increase. In a preclinical study, we observed that CETP inhibition promoted cholesterol removal from the brain and improved cognition. We commenced a Phase 2a clinical trial in early 2022 in patients with early Alzheimer's disease and the ApoE4 mutation to evaluate the pharmacodynamic and pharmacokinetic effects, safety and tolerability of obicetrapib. We currently expect to report data from this trial in 2023. Should the data from this trial warrant it, we intend to continue advancing this product candidate through the clinical development pathway.
- **Explore the potential of CETP inhibitors for use in other indications.** We believe that CETP inhibition, by markedly increasing HDL-C and lowering LDL-C, may also have a role to play in other indications by potentially mitigating the risk of developing diseases such as diabetes, which led to an estimated 1,500,000 deaths globally in 2019, in addition to CVD and Alzheimer's disease. Clinically demonstrated anti-diabetic benefits have been observed with CETP inhibition in Phase 3 CVOTs that, if seen in obicetrapib, would differentiate it from current treatment alternatives, especially statins. We are planning preclinical studies examining the potential of obicetrapib for patients suffering from diabetes and have included the onset of diabetes as an endpoint in our CVOT.

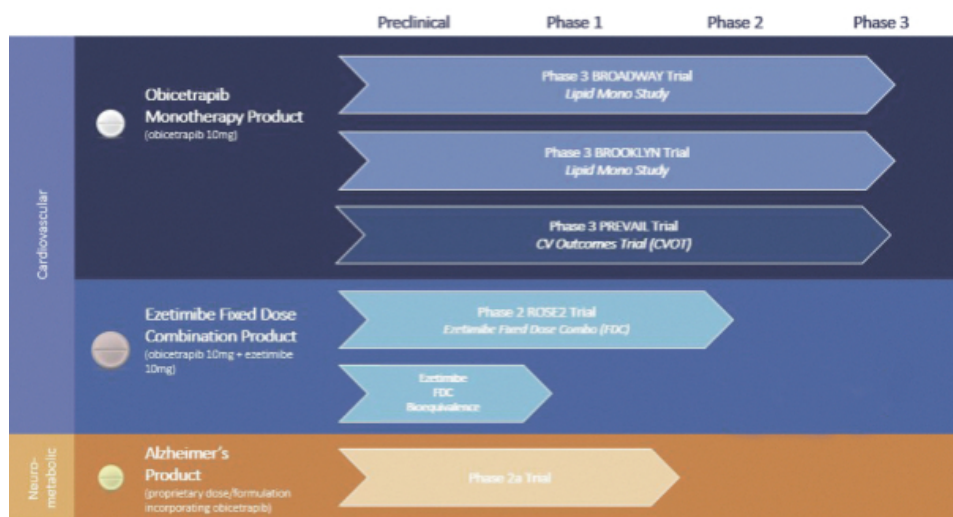
Clinical Development Plan

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

statin therapy on reduction in LDL-C. We commenced a Phase 2 dose-finding study of obicetrapib as an adjunct to stable statin therapy in patients with dyslipidemia in Japan.

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

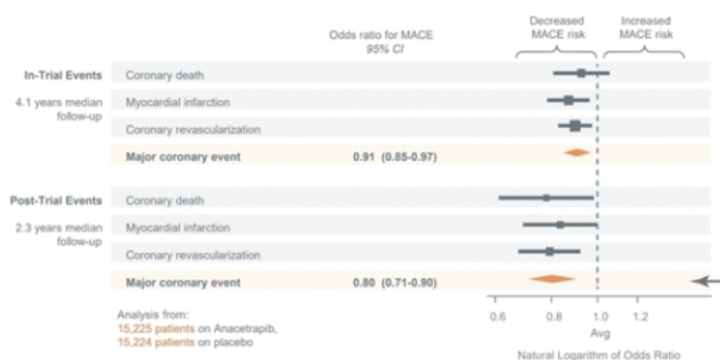
We have set forth below our current obicetrapib clinical development pipeline.



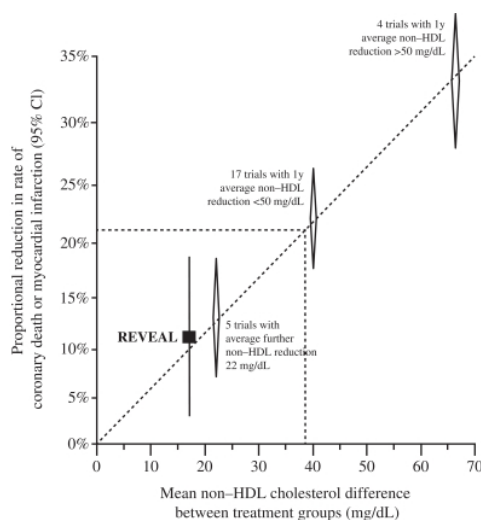
Obicetrapib for Cardiovascular Disease

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

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



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



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

With these learnings in mind, we are executing a clinical development plan for obicetrapib focused on patients with high baseline LDL-C and that is designed to support a broad CVD label, if successful. To date, we have completed seven Phase 1 trials and

three Phase 2 trials of obicetrapib. We are conducting two Phase 3 lipid trials and a third Phase 3 CVOT, and a fourth Phase 2b trial is ongoing.

Ongoing Clinical Trials for Cardiovascular Disease

Phase 3 BROADWAY and BROOKLYN Lipid Trials

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

The primary endpoint of both trials is percent change from baseline in LDL-C compared to placebo after 12 weeks. Secondary endpoints will also include percent changes from baseline compared to placebo after 12 weeks in Lp(a), ApoB, HDL-C, non-HDL-C (representing total cholesterol minus HDL-C), LDL-C from baseline to placebo after 180 days and 52 weeks, and, for BROADWAY, total cholesterol and triglycerides and MACE from baseline to 30 days after the last dose. We also expect to evaluate the safety and tolerability profile of obicetrapib in a broadly representative population of adult males and females of all ages, including elderly and very elderly participants, assessed by AEs, vital signs, clinical laboratory values and electrocardiogram ("ECG") measurements as well as to evaluate the effects of obicetrapib on blood pressure.

Phase 3 PREVAIL Cardiovascular Outcomes Trial

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

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

Phase 2b ROSE2 Trial

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

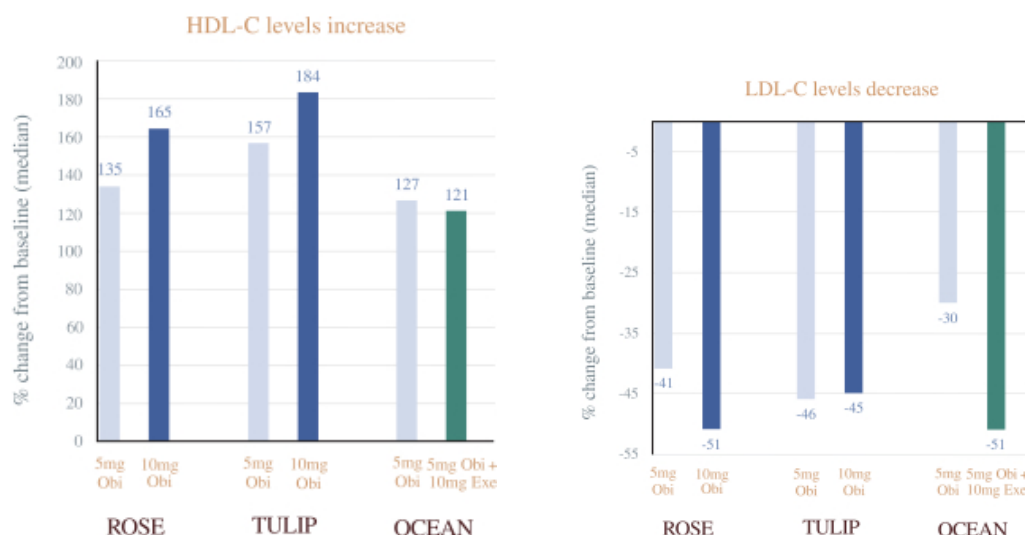
We announced the topline results from the ROSE2 clinical trial on January 17, 2023. A total of 119 patients were randomized to receive combination therapy, obicetrapib 10mg or placebo for an 84-day treatment period. The primary efficacy endpoint was the percent change from Day 1 to Day 84 in LDL-C for the combination treatment group compared to the placebo group and was met ($p < 0.0001$). Patients treated with the combination of obicetrapib and ezetimibe achieved a median reduction in LDL-C of 59%, as compared to patients treated with placebo, who achieved a median reduction in LDL-C of 6%. Overall, the combination of obicetrapib and ezetimibe was observed to be well-tolerated, with a safety profile observed to be comparable to placebo.

Phase 2 Japan Trial

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

Completed Phase 2 Clinical Trials

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



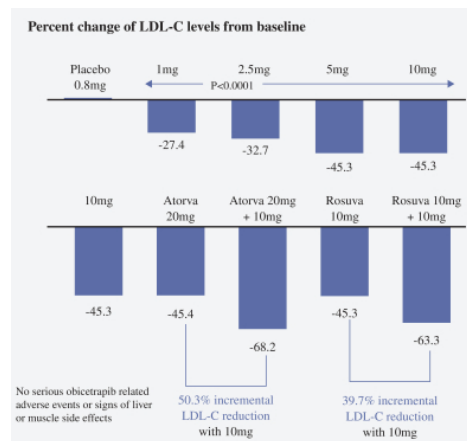
In our Phase 2b ROSE trial, we observed that obicetrapib has robust LDL-lowering capability as an adjunct to high-intensity statins at both 5 mg and 10 mg dosages. Based on our ROSE trial, we are using a 10 mg dosage for our Phase 3 trials. In our Phase 2a TULIP trial, we observed that a daily dose of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

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

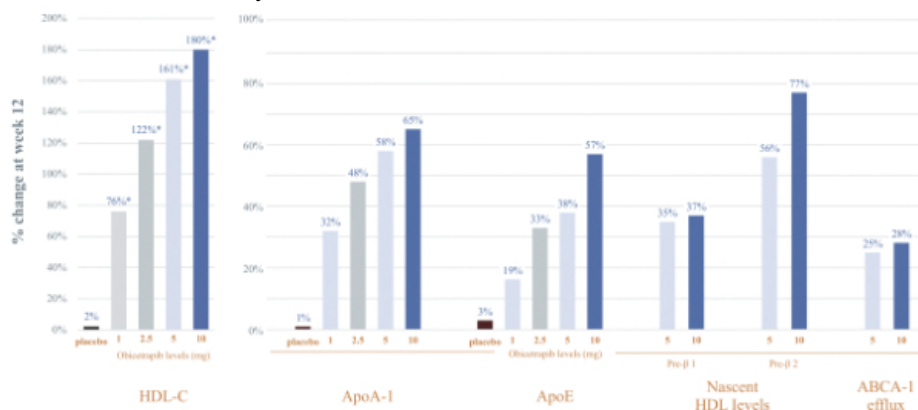
Trial	Design	Patients	Obicetrapib Formulation
TULIP (TA-8995-03)	Randomized, double-blind placebo-controlled trial to evaluate the percent changes in LDL-C and HDL-C levels	364 patients with mild dyslipidemia not on lipid-altering therapy at screening	1, 2.5, 5 or 10 mg alone and as a combination therapy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



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



Key secondary endpoints included percent changes in ApoB and apolipoprotein A1 (“ApoA1”). In patients treated with 5 mg obicetrapib, ApoB was reduced by 33.8%, while ApoA1 levels increased by 58.3%. A daily dose of 10 mg obicetrapib on top of statin therapy resulted in an ApoB reduction of 30% and an ApoA1 increase of 54.1% than those observed in patients receiving statin therapy alone. Other secondary endpoints included percent change in ApoE, nascent HDL levels and ABCA-1 efflux. A summary of certain of these results follows:



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



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

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

Time	Placebo	Obicetrapib 5mg	Obicetrapib 10mg
Baseline Median	90.0 (63, 204) N=40	95.0 (54, 236) N=39	88.0 (39, 207) N=40
EoT Median	86.0 (43, 137) N=39	53.0 (13, 126) N=39	49.5 (23, 83) N=40
% Change from Baseline (median)	-6.5 (-53.9, 31.6) N=39	-41.45 (-71.2, 62.3) N=38*	-50.75 (-76.9, 15.6) N=40
% Change from Baseline LS mean (95% CI) P-value	-4.76 (-11.74, 2.22) 0.1814	-37.98 (-44.80, -31.17) <0.0001	-44.15 (-50.95, -37.35) <0.0001

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

Percent Change from Baseline to 8 Weeks in Lipid Biomarkers

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

¹ Least squares (LS) means and p-values (two-sided) are from a mixed model for repeated measures (MMRM) model with treatment, visit and treatment-by-visit as factors and baseline LDL-C as a covariate. p-values from comparison to placebo. For percent change values, n=39 for placebo and obicetrapib 5 mg groups for all, except n=38 for LDL-C and Lp(a) for obicetrapib 5 mg.

Overall, obicetrapib as an adjunct to high-intensity statin therapy at both doses was observed to be well-tolerated compared to placebo. TEAEs were reported by 15 subjects in the 5 mg group and eight subjects in the 10 mg group, compared with 19 subjects in the placebo group. Some of the TEAEs in the study reported by more than one subject in any treatment group were muscle spasms (none in either of the obicetrapib groups and two subjects in the placebo group), fatigue (two subjects in the 5 mg group, one subject in the 10 mg group, and two subjects in the placebo group), basal cell carcinoma (none in either of the obicetrapib groups and two subjects in the placebo group), nausea (one subject in the 5 mg group and two subjects in the placebo group), Type 2 diabetes mellitus

(two subjects in the 5 mg group and none in the 10 mg or placebo groups) and hypertension (two subjects in the 5 mg group and no subjects in either the 10 mg or placebo groups). All other TEAEs were experienced by only one or no subjects in each treatment group. TEAEs that were considered by the investigator to be related to study treatment were reported by three subjects (two subjects in the 5 mg group and one subject in the 10 mg group), compared with four subjects in the placebo group. There were no TEAEs leading to death. One subject in the placebo group had a TEAE leading to discontinuation. The majority of TEAEs were mild and moderate in severity; one subject in the placebo group had a severe TEAE. There were two serious TEAEs, both of which occurred in the placebo group.

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



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

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

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

Time	Placebo	Ezetimibe 10mg	Obicetrapib 5mg	Obi 5 + Eze 10mg
Baseline Median	136.0 (101, 177) (N=24)	127.0 (76, 189) (N=27)	121.0 (82, 153) (N=27)	123.0 (89, 186) (N=27)
EoT Median	138.0 (88, 193) (N=25)	105.0 (66, 142) (N=24)	86.5 (38, 137) (N=26)	63.5 (34, 133) (N=24)
% change from BL median	-2.0 (-24.5, 35.9) (N=27)	-14.90 (-46.8, 46.9) (N=25)	-30.10 (-56.7, 19.1) (N=25)	-51.40 (-69.6, 8.1) (N=24)
% change from BL LSMean (95%CI) p-value	1.40 (-6.03, 8.84) 0.7116	-12.86 (-20.29, -5.42) 0.0007	-30.70 (-38.21, -23.19) <0.0001	-40.95 (-48.73, -33.16) <0.0001

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

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

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

Time	Placebo (N=27)	Ezetimibe 10mg (N=25)	Obicetrapib 5mg (N=26)	Obi 5mg + Eze 10mg (N=24)
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Obicetrapib 5 mg alone and as a combination therapy with ezetimibe 10 mg taken once daily for eight weeks displayed a favorable tolerability profile. TEAEs were reported by four subjects in the obicetrapib 5 mg group and nine subjects in the combination group, compared with eight subjects in the ezetimibe 10 mg group and six subjects in the placebo group. The TEAEs in the study reported by more than one subject in any treatment group were diarrhea (no subjects and two subjects in the obicetrapib 5 mg and combination groups, respectively, and two subjects and no subjects in the ezetimibe 10 mg and placebo groups, respectively) and headache (no subjects and one subject in the obicetrapib 5 mg and combination groups, respectively, and two subjects and one subject in the ezetimibe 10 mg and placebo groups, respectively). All other TEAEs were experienced by one or no subjects in each treatment group. TEAEs that were considered to be related to study treatment were reported by one subject and three subjects in the obicetrapib 5 mg and combination groups, respectively, compared with three subjects and four subjects in the ezetimibe 10 mg and placebo groups, respectively. There were no TEAEs leading to death. One subject in the ezetimibe 10 mg group had a TEAE leading to discontinuation of the study drug, compared to no subjects in the 5 mg group and two subjects in the combination group. The majority of TEAEs were mild and moderate in severity, and one subject in the ezetimibe 10 mg group had a severe TEAE.

Phase 1 Clinical Trials

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

Phase 1 Trial	Design	Treatment / Formulation	Results
TA-8995-01: Single ascending dose study in healthy Caucasian and Japanese subjects	Randomized, double-blind, single-dose, placebo-controlled trial in healthy men and women. 12 groups of 8 subjects. 2 to 6 randomized to placebo or active treatment.	Single oral dose of 5, 10, 25, 50, 100 and 150 mg obicetrapib capsules, or Single oral dose of placebo	Dose-dependent and sustained inhibition of CETP activity accompanied by a decrease in LDL-C and ApoB and increases in CETP, HDL-C, ApoA-1 and apolipoprotein E (“ApoE”). Pharmacokinetics and pharmacodynamics generally consistent across ethnicity, age and gender.
TA-8995-E02: Multiple ascending dose study in healthy subjects	Randomized double-blind, placebo-controlled, sequential, multiple ascending-dose design. 5 groups of 12 subjects randomized to placebo or active treatment. Duration of treatment: 28 days of dosing for group 1, 21 days for groups 2-5.	Multiple oral dosages of 5, 10, 2.5, 1, and 25 mg obicetrapib capsules, or Multiple oral dosages of placebo	No safety or tolerability issues observed. Single and multiple doses of up to 25 mg of obicetrapib did not yield adverse effects on vital signs or ECG changes, nor did clinical laboratory assessments and physical examinations reveal any safety issues. The maximum percent reduction in CETP activity from baseline following the 5 mg and 10 mg doses were 90.9% and 97.6%, respectively.

Phase 1 Trial	Design	Treatment / Formulation	Results
TA-8995-07: Study to assess the mass balance recovery, pharmacokinetics, metabolism and excretion of ¹⁴ C-TA-8995 in healthy male subjects	Open label, single oral dose study in 6 subjects.	10 mL ¹⁴ C-obicetrapib oral suspension, containing 10 mg and 100 µCi of ¹⁴ C-obicetrapib	Obicetrapib was steadily absorbed with a median of 4.5 hours to maximum absorption levels. Median half-life was 161 hours. A mean of 63.8% radioactivity was recovered in the feces and 15.4% in the urine, Overall total recovery of radioactivity in excreta approximately 78% of the administered dose.
TA-8995-04: Study of the electrocardiographic effects of TA-8995 in healthy male and female subjects	135 subjects randomized to one of 3 study treatments.	Single oral dose of 150 mg obicetrapib capsules, or Single oral dose of placebo, or Single open-label oral dose of 400 mg moxifloxacin	No clinically meaningful effects on any ECG parameter were observed.
TA-8995-05: A Phase 1, open label study to assess the effects of TA-8995 on the pharmacokinetics of midazolam and digoxin in healthy male subjects	Open label, crossover, fixed sequence study in 16 healthy male subjects. Duration of treatment up to 15 days.	Digoxin 0.25 mg oral tablet on the morning of Days 1 and 13 Midazolam 5 mg oral solution on the morning of Days 2 and 14 obicetrapib 25 mg (2 x 10 mg and 1 x 5 mg) oral capsules on the morning of Day 8 and 10 mg oral capsule on the morning of Days 9 to 15.	No significant effect on digoxin was observed, with a statistically significant decrease in midazolam plasma. Absorption rates of digoxin and midazolam were unaffected by the presence of multiple doses of obicetrapib.
TA-8995-08: Bioequivalence study of capsule and tablet formulations of TA-8995 in healthy male subjects	Open-label, randomized, 2 treatment period (3 days), cross-over study in 26 subjects	5 mg obicetrapib orally, either as a capsule or as a tablet in the first treatment period, and vice versa in the second treatment period.	Obicetrapib formulated as a tablet was bioequivalent to obicetrapib formulated as a capsule in terms of overall concentration over time but not in terms of the maximum observed concentration, which varied among study subjects.
TA-8995-06: A Phase 1 study of the effects of TA-8995 on Lp(a) in male and female subjects with elevated Lp(a)	Single-center, randomized, double-blind, placebo- controlled, parallel-group	TA-8995 10 mg once daily, TA-8995 2.5 mg once daily, or matching placebo once daily.	There were statistically significant reductions in Lp(a) in both the TA-8995 2.5 mg and 10 mg groups, compared with placebo, at week 12 (primary endpoint) and at week 4 (secondary endpoint). There were statistically significant increases in HDL-C, ApoA1, and ApoE levels and decreases in LDL-C and ApoB levels, at week 12, for both the TA-8995 2.5 mg and 10 mg groups, compared with placebo. TA-8995 2.5 mg and 10 mg once daily for 12

Phase 1 Trial	Design	Treatment / Formulation	Results
TA-8995-09: A randomized, open-label, two-sequence, two-period, two-treatment crossover study to evaluate the effect of food on the bioavailability of obicetrapib tablets in healthy adult subjects	Open-label, single-dose, randomized, 2-sequence, 2-period, 2-treatment crossover study in 30 subjects	10 mg obicetrapib tablets orally administered either after an overnight fast of at least 10 hours (Treatment T1, fasted) or at 30 minutes after the start of a completed standardized high-fat, high-calorie breakfast that was preceded by an overnight fast of at least 10 hours (Treatment T2, fed)	weeks was generally well tolerated in subjects with elevated Lp(a) levels. Based on the plasma concentration data for obicetrapib, the peak and overall systemic exposure were 55-59% greater under fed conditions compared to that of fasted conditions. The least-squares geometric mean of fed versus fasted ratios were 154.87%, 155.42% and 158.53% for AUC _{0-t} , AUC _{0-∞} and C _{max} , respectively.

Obicetrapib for Other Therapeutic Areas

Alzheimer's disease

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

In a healthy brain, excess cholesterol levels in the neurons and amyloid-beta ("Ab") peptide removal from cerebral spinal fluid are regulated properly. The brain is the most cholesterol-rich organ in the body; comprising only two percent of the body's mass, it contains approximately 20% of the body's cholesterol, which is recycled and redistributed through an ApoE-mediated lipoprotein pathway. Inside populations of cells called astrocytes, ApoE binds with cholesterol that has been released into the brain by neurons and converts it into a different form of cholesterol that is transported out of the brain into the systemic circulation. In addition to ApoE, the protein associated with HDL, ApoA1, also acts as the brain's "vacuum cleaner," by removing toxic cholesterol from peripheral tissue to promote healthy cell function and survival. In addition, small HDL particles that transverse the blood brain barrier remove excess Ab peptides in cerebral spinal fluid for ultimate conversion and transport out of the brain.

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

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

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

Manufacturing and Supply

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

Marketing and Sales

We do not currently have our own marketing, sales or distribution capabilities. In order to commercialize obicetrapib or any future product candidates, if approved for commercial sale, we currently plan to develop our own sales and marketing infrastructure in the United States and have entered, and expect to continue to enter, into arrangements with third parties to perform these services outside of the United States. We may also opportunistically seek strategic collaborations to maximize the commercial opportunities for our future product candidates inside and outside the United States. We have entered into a license agreement with Menarini, pursuant to which Menarini has been granted the exclusive rights to commercialize obicetrapib 10 mg either as a sole active ingredient product or in a fixed dose combination with ezetimibe in the majority of European countries, if approved. As any future product candidates near regulatory approval and potential commercial launch, we plan to assess our options for commercializing each respective product candidate and may choose to commercialize themselves ourselves or with a partner.

Menarini License

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

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

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

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

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

Through December 31, 2022, we have not received any milestone payments from Menarini under the Menarini License. In January 2023, we achieved a clinical success milestone related to our Phase 2b ROSE2 clinical trial and as a result expect to receive the milestone payment from Menarini by April 2023.

Intellectual Property

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

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

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

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

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

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

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

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

For more information regarding the risks related to our intellectual property, please see “*Item 3. Key Information—D. Risk Factors—Risks Related to Our Intellectual Property.*”

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

Obicetrapib First Generation Patents

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

In North America outside of the United States, we have one granted patent in Canada and one granted patent in Mexico. In addition we have 13 granted patents in other foreign jurisdictions. Patent applications are pending in Argentina and Thailand. Patents, and patent applications, if granted, are expected to expire between April 2025 and August 2027, without taking potential patent term extensions into account. The first generation portfolio also includes a patent family covering a method of synthesizing obicetrapib. We have one patent in the United States, five patents in Europe including the United Kingdom, and one patent in Japan. Patents in this family are expected to expire between March 29, 2027 and March 31, 2029, not including patent term extensions.

Obicetrapib Second Generation Patents

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

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

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

Obicetrapib Third Generation Patents

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

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

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

Trade Secrets

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

Competition

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

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

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

Government Regulation and Product Approval

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

U.S. Drug Development Process

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

- completion of preclinical laboratory tests, animal studies, and formulation studies in accordance with FDA's Good Laboratory Practice requirements and other applicable regulations;
- submission to the FDA of an IND application, which must become effective before human clinical trials may begin and must be updated annually and when certain changes are made;
- approval by an independent IRB, or independent ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with GCPs, to establish the safety and efficacy of the proposed drug for its intended use;
- preparation of and submission to the FDA of an NDA after completion of pivotal trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the application for review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA audit of the nonclinical study and/or clinical study sites that generated data in support of the NDA; and
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States.

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

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, dosing procedures, subject selection and exclusion criteria, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site

proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

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

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

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

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

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

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

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

U.S. Review and Approval Process

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

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

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates, and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

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

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

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

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

U.S. Expedited Development and Review Programs

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

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

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

Additionally, product candidates studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may utilize an accelerated approval pathway upon a determination that the product has an effect on (1) a surrogate endpoint that is reasonably likely to predict clinical benefit or (2) a clinical endpoint that can be measured earlier than irreversible morbidity or

mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Products receiving accelerated approval may be subject to withdrawal of its approval if, for example, the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, for products being considered for accelerated approval, the FDA generally requires, unless otherwise informed by the agency, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency for review during the pre-approval review period, which could adversely impact the timing of the commercial launch of the product.

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

U.S. Marketing Exclusivity

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

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active ingredient for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a 505(b)(1) NDA; however, an applicant submitting a 505(b)(1) NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

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

U.S. Post-approval Requirements

Drug products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product, which include restrictions on promoting products for unapproved uses or patient populations (known as “off-label use”) and limitations on industry-sponsored scientific and educational activities. In rare cases, pre-approval of promotional materials may be required. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. Further, for certain modifications to the drug, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be

required to submit and obtain prior FDA approval of a new NDA or NDA supplement, which may require the development and submission of additional data. There also are continuing, annual program fees for any marketed products. Drug manufacturers and their subcontractors involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements. Manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and other tracking requirements and must notify the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or untitled letters;
- clinical holds on clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications or suspension or revocation of product approvals;
- product seizure or detention or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases, and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

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

Other Healthcare Laws

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

The U.S. federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving, or providing any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering, or arranging for, or recommending the purchase, lease, or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid, or other federal healthcare programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

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

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

HIPAA, created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”), and their respective implementing regulations, which impose obligations on “covered entities,” including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective “business associates” and their respective subcontractors that create, receive, maintain, or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information.

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

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

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

require tracking gifts and other remuneration and items of value provided to physicians, other healthcare providers and entities; and state and local laws that require the registration of pharmaceutical sales representatives.

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

Coverage and Reimbursement

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

Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication, or place products at certain formulary levels that result in lower reimbursement levels and higher cost-sharing obligation imposed on patients. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, and they often require us to provide scientific and clinical support for the use of our products to each payor separately, which can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Additionally, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved.

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

Healthcare Reform

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

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

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

introduced a quality payment program under which certain individual Medicare providers will be subject to certain incentives or penalties based on new program quality standards. In November 2019, CMS issued a final rule finalizing the changes to the Medicare Quality Payment Program.

There has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 30, 2020, HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The IRA delayed the implementation of the rule to January 1, 2032. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers; the implementation of these provisions has also been delayed by the IRA until January 1, 2032. In addition, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate price cap, currently set at 100% of a drug's average manufacturer price for single source and innovator multiple source products, beginning on January 1, 2024. Further, in July 2021, the Biden Administration released an executive order that included multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug price reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions by HHS. No legislative or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of the budget reconciliation process. Additionally, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subjects drug manufacturers to civil monetary penalties and a potential excise tax for offering a price that is not equal to or less than the negotiated "maximum fair price" under the law, and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry.

Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, mechanisms to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

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

Data Privacy and Security Laws

Numerous state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, including HIPAA, and federal and state consumer protection laws and regulations (e.g., Section 5 of the Federal Trade Commission Act) that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, certain state and non-U.S. laws, such as the California Consumer Privacy Act ("CCPA"), the California Privacy Rights Act ("CPRA") and the GDPR, govern the privacy and security of personal

information, including health-related information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations and other obligations are constantly evolving, may conflict with each other to make compliance efforts more challenging, and can result in investigations, proceedings, or actions that lead to significant penalties and restrictions on data processing.

Regulation and Procedures Governing Approval of Medicinal Products in the EU

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

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

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

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

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

EU Non-Clinical Studies and Clinical Trials

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

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

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

The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the EU. The main characteristics of the regulation include: a streamlined application procedure via a single-entry point, the “EU portal”; a single set of

documents to be prepared and submitted for the application, as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU member states in which an application for authorization of a clinical trial has been submitted (member states concerned). Part II is assessed separately by each member state concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU member state. However, overall related timelines are defined by the Clinical Trials Regulation.

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

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

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

EU Marketing Authorizations

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

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

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

Under the centralized procedure in the EU, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product targeting an unmet medical need is expected to be of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150

days (not including clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

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

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

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

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines (“PRIME”), scheme, which provides incentives similar to the breakthrough therapy designation in the United States. PRIME is a voluntary scheme aimed at enhancing the EMA’s support for the development of medicinal products that show the potential to target unmet medical needs. It permits increased interaction and early dialogue with companies developing promising medicinal products, to optimize their product development plans and speed up their evaluation to help the product reach patients as early as possible. Product developers that benefit from PRIME designation are potentially eligible for accelerated assessment of their MAA although this is not guaranteed. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

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

An MA may also be granted “under exceptional circumstances” where the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information or when generating data may be contrary to generally accepted ethical principles. Like a conditional MA, an MA granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not

hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data on the medicinal product's efficacy and safety under normal conditions of use. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the MA is withdrawn in case the risk-benefit ratio is no longer favorable.

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

EU Data and Market Exclusivity

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

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

EU Post-Approval Requirements

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

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

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

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

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

Japanese Drug Regulation

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

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

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

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

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

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

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

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

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

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

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

PRC Regulatory Authorities and Recent Government Reorganization

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

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

PRC Breakthrough Therapy Designation by the NMPA

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

PRC Non-Clinical Research

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

PRC Clinical Trials and Regulatory Approval

Upon completion of preclinical studies, a sponsor will often need to conduct clinical trials in China to support registration. The materials required for a clinical trial application are substantial even at the CTA stage, including detailed manufacturing information. Drug registration trials in China many only be conducted after obtaining approval of a CTA submitted to CDE, approval of the ethics committee at each accredited hospital site, and human genetic resource approval (“HGR”), which is required for the collection of samples and associated data. CTAs may be approved in 60 business days if there is no comment from CDE, and the other applications

can take approximately 3-4 months each. Information about clinical trials must be registered on an NMPA-administered platform and continually updated during the trial, and certain information, not including the protocol, is made publicly available on the platform.

PRC Trial Exemptions and Acceptance of Foreign Data

The NMPA may reduce requirements for clinical trials and data, depending on the drug and the existing data. In some cases, NMPA has granted waivers for all or part of trials and has stated that it will accept data generated abroad (even if not part of a global study with a site in China), including early phase data, that meets its requirements. According to the Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data the data from foreign clinical trials must meet China's authenticity, completeness, accuracy, and traceability requirements, and be obtained consistent with the relevant requirements under the China's Drug GCP. Sponsors must be attentive to potentially meaningful ethnic differences in the subject populations.

PRC Clinical Trial Process and Good Clinical Practices

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

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

PRC Drug Marketing Application and Approval

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

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

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

Employees and Human Capital Resources

As of December 31, 2022, we had 17 full-time employees, consisting of clinical, research and development, business development, regulatory, finance and operational personnel, who are employed through our wholly owned subsidiary in the United States, NewAmsterdam Pharma Corporation. None of our employees are subject to a collective bargaining agreement. We consider our relationship with our employees to be good. We have also engaged consultants to assist with our clinical development and regulatory obligations. Our Dutch wholly owned subsidiary, NewAmsterdam Pharma B.V., engages a total of nine independent contractors. These independent contractors provide a diverse array of services, which includes assisting with our clinical development and regulatory obligations.

NewAmsterdam Pharma does not directly employ anyone or engage any independent contractors (*zelfstandigen zonder personeel*). No Works Council or other employee representative body (*personeelsvertegenwoordiging*) is established within NewAmsterdam Pharma Holding B.V. or NewAmsterdam Pharma B.V.

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

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

Legal Proceedings

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

C. ORGANIZATIONAL STRUCTURE

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

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

D. PROPERTY, PLANTS AND EQUIPMENT

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

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

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

COVID-19 Impact on Facilities

We have implemented policies that enable our employees to work remotely, and such policies may continue for an indefinite period. We continue to evaluate our protocols and practices as the global response to the COVID-19 pandemic continues to evolve and

continue to adhere to local, state and federal guidelines. While we are partially operating virtually in light of the COVID-19 pandemic, we believe our operational needs are being met for the time being. To date, we have not experienced any material impact on our ability to operate our business. We plan to periodically reassess the impact of COVID-19 on our facility needs.

ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements, including the notes thereto, included in this Annual Report. Our consolidated financial statements are presented in euros and have been prepared in accordance with IFRS. Financial statements prepared in accordance with IFRS may differ in material respects from generally accepted accounting principles in other jurisdictions, including U.S. GAAP but which our management believes is relevant to an assessment and understanding of our financial condition and results of operations. The following discussion includes forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those described under “Special Note Regarding Forward-Looking Statements” and “Item 3. Key Information—D. Risk Factors” included elsewhere in this Annual Report.

For a discussion of our consolidated statements of operations for the year ended December 31, 2020 and our cash flows for the year ended December 31, 2020, and a discussion of our results of operations for the year ended December 31, 2021 as compared to the year ended December 31, 2020, refer to the section titled “Management’s Discussion And Analysis Of Financial Condition And Results Of Operations” in the Registration Statement on Form F-1 ([File No. 333-268888](#)) filed on January 17, 2023.

A. OPERATING RESULTS

Overview

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

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

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

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

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

Our goal is to develop and commercialize a LDL-lowering monotherapy and combination therapy, which offers the cost and convenience advantages of a once-daily oral pill, and fulfills the significant unmet need for an effective and convenient LDL-lowering

therapy. If we obtain marketing approval, we intend to commercialize obicetrapib for patients suffering from CVD independently and with strategic partners in certain jurisdictions. We have partnered with Menarini, to provide them with the exclusive rights to commercialize obicetrapib either as a sole active ingredient product or in a fixed dose combination with ezetimibe in the majority of European countries, if approved. Subject to receipt of marketing approval, our current plan is to pursue development and commercialization of obicetrapib in the United States ourselves, and to consider additional partners for jurisdictions outside of the United States and the EU, including in Japan, China and the United Kingdom.

Recent Developments

Impact of the COVID-19 Pandemic and the Conflict in Ukraine

As a result of the spread of the COVID-19 pandemic and the Russian invasion of Ukraine, economic uncertainties have arisen which may negatively affect our financial position, results of operations and cash flows. These uncertainties include, among other things, downturns in the financial markets or in economic conditions, increases in oil prices, inflation, increases in interest rates, supply chain disruptions, and declines in consumer confidence and spending. We have assessed that the COVID-19 pandemic and the conflict in Ukraine did not have a material or direct impact on our operations or financial position. Nevertheless, in light of the ongoing COVID-19 pandemic, we have implemented measures to protect employees and take social responsibility while at the same time attempting to limit any negative effects on our business. The duration of uncertainties and the ultimate financial effects resulting from the ongoing COVID-19 pandemic and the conflict in Ukraine cannot be reasonably estimated at this time. We will continue to monitor these situations very closely and implement further measures if we believe they are required.

Completion of Business Combination

On November 22, 2022, we completed the Business Combination and the PIPE Financing. See “*Item 4. Information on the Company—A. History and Development of the Company*” for a more detailed description of these transactions. Upon consummation of the transactions, we became a public company. Our Ordinary Shares are traded on The Nasdaq Global Market under the symbol “NAMS” and our Public Warrants are traded on The Nasdaq Global Market under the symbol “NAMS.W.”

Resale Registration Statement

On December 20, 2022, we filed the Resale Registration Statement with the SEC, registering up to 77,092,642 Ordinary Shares for resale by certain of our securityholders, representing approximately 89.3% of our issued and outstanding Ordinary Shares as of December 31, 2022 (assuming that all Warrants are exercised). Following the expiration of the applicable lock-up restrictions, the sale of all Ordinary Shares registered for sale pursuant to the Resale Registration Statement, including Ordinary Shares issuable upon the exercise of the Warrants, or the perception that such sales may occur, may cause the market prices of our securities to decline significantly and could impair our ability to raise capital through the sale of additional equity securities.

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. Pursuant to the Menarini License, we received a non-refundable, non-creditable upfront amount of €115.0 million from Menarini on July 7, 2022, of which €93.5 million was recognized as revenue upon the execution of the Menarini License on June 23, 2022 and €4.0 million was subsequently recognized as revenue in 2022. Additionally, in partial contribution 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, out of our control, the fixed €27.5 million is considered constrained at contract execution and is not initially recognized within the transaction price until it becomes highly probable of no significant revenue reversal. At the end of each reporting period, we will assess the probability of significant reversals for any amounts that become likely to be realized prior to recognizing the fixed consideration associated with these payments within the transaction price.

Under the Menarini License, we are also entitled to receive fixed reimbursement payments for our continued development costs, certain cost sharing payments, sales-based royalties, as well as payments based upon the achievement of defined development, regulatory and commercial milestones. These milestones are contingent payments and represent variable considerations that are not initially recognized within the transaction price. 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. We did not achieve any milestones pursuant to the Menarini License in the year ended December 31, 2022 but did achieve a milestone in January 2023 in connection with the announcement of topline data from our ROSE2 trial. At the end of each reporting period, we will assess the probability of significant reversals for any amounts that become likely to be realized prior to recognizing the variable consideration associated with these payments within the transaction price.

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 statement of financial position 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. We commenced a Phase 3 CVOT trial and two other Phase 3 trials in 2022. Much of our current focus in the Phase 3 trials is on project startup activities, the search for qualified investigator sites and patient enrollment and screening. 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 active pharmaceutical ingredient (“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, primarily for costs incurred by CROs assisting with an ongoing two-year rat and hamster carcinogenicity study; and
- other clinical costs such as clinical trial insurance and other consultancy fees.

We expect our research and development expenses to increase substantially in the future 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 “*Item 3. Key Information—D. 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 our planned substantial increase in research and development expenses, as discussed above, we also 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.

Finance Income

Finance income is recognized using the effective interest rate method and is related to the €709 thousand loan provided to our chief executive officer, Michael Davidson, M.D., pursuant to the loan agreement, dated June 28, 2021 (the “Davidson Loan Agreement”). The principal amount of the Davidson Loan Agreement was used to pay for depository receipts issued by Stichting Administratiekantoor NewAmsterdam Pharma, a Dutch foundation which holds shares on behalf of certain of our shareholders, to Dr. Davidson.

On July 19, 2022, Dr. Davidson repaid the entire principal amount outstanding under the Davidson Loan Agreement, plus outstanding unpaid interest.

Finance Expense

Finance expense is recognized using the effective interest rate method and relates to our negative interest charged on cash balances and the interest on lease liabilities.

Net Foreign Exchange Gain/Loss

Our exchange gain relates mainly to cash balances denominated in foreign currencies, but also to transactions denominated in foreign currencies, mainly in U.S. Dollars, British Pounds, Canadian Dollars and Japanese Yen, which generate exchange gains and losses. As at December 31, 2022, our net exposure to foreign currency risk was €268.2 million, compared to €15.9 million as at December 31, 2021, mainly related to the U.S. Dollar.

Income Tax

We have a history of losses and therefore have not paid corporate tax. We expect to continue incurring losses as we continue to invest in our clinical and preclinical development programs. Consequently, we do not have any deferred tax assets on our statement of financial position.

Results of Operations

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

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

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

Revenue

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

Research and Development Expenses

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

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

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

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

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

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

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

Selling, General and Administrative Expenses

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

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

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

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

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

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

Share Listing Expense

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

Finance Expense

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

Fair Value Change - Earnout and Warrants

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

Foreign Exchange Gains/(Losses)

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

Income Tax

We recorded no income tax expense for both the year ended December 31, 2021 and 2022. We have a history of losses and therefore pay no corporate tax. We have not recognized deferred tax assets relating to losses carried forward as we have no products approved for sale, and it is not probable that the loss carryforwards will be utilized.

Loss for the Year

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

B. LIQUIDITY AND CAPITAL RESOURCES

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

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

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

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

We have historically funded our operations primarily through private placements of shares, the sale of convertible notes and the proceeds from the Business Combination. As at December 31, 2022, we had cash of €438.5 million. Based on our current operating plan, we believe that our existing cash, including the upfront payment of €115 million received from the Menarini License in July 2022, will be sufficient to fund our anticipated level of operations through 2026. We may consider raising additional capital to pursue strategic investments, to take advantage of financing opportunities or for other reasons. Until we can generate substantial product revenues, if ever, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, convertible loans, warrants, collaborations, or other means. We may consider raising additional capital to take advantage of favorable market conditions or for other strategic considerations even if we have sufficient funds for planned operations. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or privately placed equity offerings of securities, the terms of these securities or offerings may include liquidation or other preferences that adversely affect our

other shareholders' rights. To the extent that we raise additional funds by issuing and selling equity or equity-linked securities, shareholders will experience dilution. If we raise additional capital through debt financing, we would likely be subject to fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, licensing or selling assets, making capital expenditures or declaring dividends. Capital may become difficult or impossible to obtain due to poor market or other conditions outside of our control. If we are unable to raise sufficient additional funds on favorable terms as and when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to others any of our potential future product candidates that we would prefer to develop and commercialize ourselves. See the section of this Annual Report entitled "*Item 3. Key Information—D. 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.

Sources of Liquidity

Convertible Loan Agreement

On July 2, 2020, we, as borrower, entered into the Convertible Loan Agreement (the "Convertible Loan Agreement") with certain investors, granting us up to €17 million across three tranches of €5.7 million each (the "Convertible Loan"). In January 2021, the Convertible Loan Agreement was terminated and the full amount of outstanding principal amount and unpaid interest was converted into 1,111,155 convertible preferred series A shares in the share capital of NewAmsterdam Pharma (the "Series A Preferred Shares") in connection with the entry into a share subscription agreement (the "Series A Subscription Agreement") with various investors for up to an aggregate purchase price of €160 million (the "Series A Financing"). See "*—Series A Financing*" below for more information.

Series A Financing

On December 30, 2020, we entered into the Series A Subscription Agreement to issue Series A Preferred Shares at a subscription price per share of €14 (the "Subscription Price") for certain investors and €10.50 (equal to 75% of the Subscription Price) (the "Discounted Subscription Price") for the parties to the Convertible Loan Agreement as a set off against the Convertible Loan, for up to an aggregate amount of €160 million, occurring in two tranches. In the first tranche, we issued and sold 4,928,573 Series A Preferred Shares for gross proceeds of €69 million. The first tranche closed in January 2021 (the "First Closing"). In accordance with the terms of the Convertible Loan Agreement, €11.7 million of outstanding principal amount and unpaid interest was converted into 1,111,155 Series A Preferred Shares at the First Closing. We were entitled 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. We issued the second tranche of Series A Preferred Shares in February 2022 resulting in gross proceeds to us of €80 million and the issuance of 5,691,430 additional Series A Preferred Shares. See "*Item 7. Major Shareholders and Related Party Transactions—B. Related Party Transaction—Series A Financing*" for more information. Though the Convertible Loan and Series A Financing have historically been a source of liquidity for us, no additional funds can be generated by the Convertible Loan Agreement or the Series A Subscription Agreement.

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. 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 “*Item 4. Information on the Company—B. Business Overview—Marketing and Sales*” for a full description of the Menarini License.

Through December 31, 2022, we have received no milestone payments from Menarini under the Menarini License. In January 2023, we achieved a clinical success milestone related to our Phase 2b ROSE2 clinical trial and as a result expect to receive the milestone payment from Menarini in April 2023.

Business Combination and PIPE Financing

In July 2022, we entered into a Business Combination Agreement with FLAC, a special purpose acquisition company sponsored by the Sponsor, NewAmsterdam Pharma and Merger Sub. In connection with the Business Combination, NewAmsterdam Pharma effected the Exchange on November 21, 2022. Immediately after giving effect to the Exchange, we effected the Holdco Reorganization. Following the Holdco Reorganization, Merger Sub merged with and into FLAC, with FLAC surviving the Merger as the wholly owned subsidiary of the Company, with the Company becoming a publicly traded company listed on the Nasdaq in the United States. NewAmsterdam Pharma’s shareholders had a controlling interest in the Company following the closing of the Business Combination. The transaction closed on November 22, 2022.

Concurrently with the execution of the Business Combination Agreement, we and FLAC also entered into subscription agreements (each a “Subscription Agreement”) with certain investors, pursuant to which the PIPE Investors agreed to subscribe for and purchase from us, and we agreed to issue and sell to such PIPE Investors, an aggregate of 23,460,000 Ordinary Shares at \$10.00 per share for gross proceeds of \$234.6 million. The PIPE Financing closed substantially concurrently with the Business Combination. The Ordinary Shares issued in the PIPE Financing have not been registered under the Securities Act in reliance upon the exemption provided in Section 4(a)(2) of the Securities Act.

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.

Warrants

As of December 31, 2022, we had 4,767,000 outstanding Warrants to purchase 4,767,000 Ordinary Shares, exercisable at an exercise price of \$11.50 per share, which 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 \$54.8 million assuming the exercise of all Warrants. 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. There can be no assurance that all of our Warrants will be in the money prior to their expiration and, as such, any or all of our Warrants may expire worthless. As such, it is possible that we may never generate any 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. To the extent such Warrants are exercised, additional Ordinary Shares will be issued, which will result in dilution to the holders of our Ordinary Shares and increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market could adversely affect the market price of the Ordinary Shares.

Cash Flows

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

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

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

Net Cash Flows from Operating Activities

During the year ended December 31, 2022, net cash provided by operating activities was €8.0 million, largely driven by research and development expenses incurred as a result of spending related to the initiation of our Phase 3 clinical trials and selling, general and administrative expenses incurred as a result of activities related to the Business Combination and Menarini License, offset by the upfront fee received pursuant to the Menarini License. See “Item 5. Operating and Financial Review and Prospects—A. Operating Results—Results of Operations” for more information.

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

Net Cash Flows from Investing Activities

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

Net Cash Flows from Financing Activities

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

Contractual Obligations and Commitments

Third-Party Service Agreements

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

Leases

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

2020 SPA and Profit Right Agreement

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

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

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

- (a) shortly after the Exchange, and prior to the consummation of the Business Combination, a number of Ordinary Shares, in the aggregate, equal to (i) 17.63% of the number of shares of NewAmsterdam Pharma outstanding immediately prior to the

consummation of the Exchange on a fully diluted basis, multiplied by (ii) the exchange rate applicable to all of holders of NewAmsterdam Pharma shares in the Exchange and then (iii) rounded to the nearest whole number where an entitlement to five-tenths (0.5) of an Ordinary Share shall be rounded up; and

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

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

Menarini License

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

C. RESEARCH AND DEVELOPMENT, PATENTS AND LICENSES, ETC.

See “*Item 4. Information on the Company—B. Business Overview*” and “*Item 5. Operating and Financial Review and Prospects—A. Operating Results.*”

D. TREND INFORMATION

See “*Item 5. Operating and Financial Review and Prospects—A. Operating Results.*”

E. CRITICAL ACCOUNTING ESTIMATES

We refer to “*Note 3 - Use of Judgments and Estimates*” to our consolidated financial statements included elsewhere in this Annual Report.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. DIRECTORS AND SENIOR MANAGEMENT

Board of Directors

Our Board of Directors currently consists of one executive director and seven non-executive directors of which one has been appointed as temporary non-executive director by the Board of Directors until their proposed appointment as non-executive director

by the General Meeting. The Board of Directors has appointed Janneke van der Kamp as a temporary non-executive director effective April 1, 2023. The following table lists the names, ages as of date hereof, positions and terms of our directors.

Name	Age	Year in which Term Expires	Position
Executive Director			
Michael Davidson, M.D.	66	2025	Chief Executive Officer, Director
Non-Executive Directors			
John Kastelein, M.D.	69	2023	Director
James N. Topper, M.D., Ph.D.	61	2025	Director
Juliette Audet	37	2024	Vice Chairperson, Director
Louis Lange, M.D., Ph.D.	74	2024	Director
Sander Slootweg	54	2023	Chairperson, Director
Nicholas Downing, M.D.	37	2023	Director
John W. Smither	70	2023	Temporary Director
Janneke van der Kamp*	48	2023	Temporary Director

*Ms. van der Kamp's appointment to the Board will be effective April 1, 2023.

Executive Director

Dr. Michael Davidson. Michael Davidson, M.D., was appointed as our Chief Executive Officer and executive director in November 2022. Dr. Davidson served NewAmsterdam Pharma as its Chief Executive Officer and an executive director from August 2020 to November 2022. Prior to joining NewAmsterdam Pharma, Dr. Davidson was the founder and Chief Executive Officer of Corvidia Therapeutics, Inc. from January 2016 until April 2018 and the Chief Science/Medical Officer from April 2018 until July 2020, when Corvidia was acquired by Novo Nordisk A/S for up to \$2.1 billion. Dr. Davidson, who is a leading expert in the field of lipidology and was named in The Best Doctors in America for the past 15 years, is also currently a professor of medicine and director of the lipid clinic at the University of Chicago. Dr. Davidson co-founded and served as the Chief Medical Officer of Omthera Pharmaceuticals, Inc. in 2008, which was later acquired by AstraZeneca Pharmaceuticals in 2013 for up to \$443 million. His research background encompasses both pharmaceutical and nutritional clinical trials including extensive research on statins, novel lipid-lowering drugs, and omega-3 fatty acids. Dr. Davidson is board-certified in internal medicine, cardiology, and clinical lipidology and served as President of the National Lipid Association from 2010 to 2011. Dr. Davidson currently serves on the board of directors of Tenax Therapeutics, Inc. (Nasdaq: TENX) and Silence Therapeutics plc (Nasdaq: SLN). Dr. Davidson also serves on the boards of two private biotechnology companies, Sonothera and NanoPhoria Bioscience. Dr. Davidson received his B.A. and M.S. from Northwestern University and his M.D. from The Ohio State University School of Medicine.

We believe Dr. Davidson's extensive experience in the field of cardiology and his prior management experience provide him the qualifications and skills to serve on the Board of Directors.

Non-Executive Directors

Dr. John Kastelein. John Kastelein, M.D., Ph. D. FESC, was appointed as our Chief Scientific Officer and non-executive director in November 2022. Dr. Kastelein co-founded NewAmsterdam Pharma in 2020 served as its Chief Scientific Officer and an executive director from January 1, 2020 to November 2022. Dr. Kastelein has also served as the chief executive officer of Vascular Research Network Inc. ("VRN") since January 2013 and as the Chief Medical Officer of Staten Biotechnology B.V. since January 2018. Dr. Kastelein also serves as emeritus professor of medicine and was the chair of the department of vascular medicine at the Academic Medical Center of the University of Amsterdam. He serves on the advisory board of the Dutch Atherosclerosis Society. In 2011 he received the ZonMw Pearl for his research in the field of gene therapy. Dr. Kastelein also serves on the board of directors of North Sea Therapeutics Inc., VRN and Oxitope Pharma Inc. Dr. Kastelein also serves as an advisor to a number of biotech and pharmaceutical companies. Dr. Kastelein was awarded a doctorate in medicine (with honors) from the University of Amsterdam, trained in internal medicine at the Academic Medical Center of the University of Amsterdam, and trained in lipidology and molecular biology at the University of British Columbia in Vancouver. Dr. Kastelein published his first clinical research on CETP-inhibition in the New England Journal of Medicine in 1997.

We believe Dr. Kastelein's deep scientific and medical knowledge about NewAmsterdam Pharma's product candidate and his experience in senior management provide Dr. Kastelein with the qualifications and skills to serve on the Board of Directors.

Dr. James N. Topper. James N. Topper, M.D., Ph.D., was appointed to the Board of Directors in November 2022. Dr. Topper previously served as FLAC's Chief Executive Officer and Chairman of the FLAC Board from October 2020 until November 2022. Dr. Topper currently serves as a Managing Partner of Frazier Life Sciences ("Frazier"). He joined Frazier in 2003 and opened Frazier's Menlo Park office in the same year. Throughout his 15 years as a Managing Partner, Dr. Topper has invested across over 35 companies encompassing a broad spectrum of life science and biopharmaceutical companies. Dr. Topper has led and served as a board member for many of Frazier's successful life sciences investments, including Acerta Pharma BV (sold to AstraZeneca), Amunix Pharmaceuticals, Inc. (sold to Sanofi), Aptinyx Inc. (Nasdaq: APTX), Calistoga Pharmaceuticals, Inc. (co-founder, sold to Gilead Sciences), Entasis Therapeutics Holdings Inc. (sold to Innoviva), Frazier Lifesciences Acquisition Corporation, Mavupharma (sold to AbbVie), Rempex (sold to The Medicines Company), Incline (co-founder, sold to The Medicines Company), Alnara (sold to Lilly), Portola, Inc. (co-founder, Nasdaq: PTLA), Phathom Pharmaceuticals Inc. (Nasdaq: PHAT), CoTherix, Inc (sold to Actelion), and Threshold Pharmaceutical, Inc. (Nasdaq: THLD). He currently represents Frazier on the boards of Alpine Immune Sciences (Nasdaq: ALPN), AnaptysBio, Inc. (Nasdaq: ANAB), Lassen Therapeutics, Seraxis Holdings, Inc., Enlaza Therapeutics, Inc., Serum, Inc. and Sudo Biosciences, Inc. In 2011 and 2016, Dr. Topper was named to the Midas List of leading venture capitalists, and in 2013, Dr. Topper was recognized by Forbes as a top ten healthcare investor. Dr. Topper received his M.D. and Ph.D. in Biophysics from Stanford and his B.S. from the University of Michigan.

We believe that Dr. Topper's experience overseeing Frazier's investments in biotechnology, his experience in senior management positions and his significant knowledge of industry, medical and scientific matters, provide Dr. Topper with the qualifications and skills to serve on the Board of Directors.

Juliette Audet. Juliette Audet was appointed to the Board of Directors in November 2022. Ms. Audet previously served on the NewAmsterdam Pharma board from 2020 until November 2022. Ms. Audet has been a partner at Forbion Venture Capital since January 2021 and served as a principal at Forbion from October 2019 until December 2020. Prior to joining Forbion, Ms. Audet was a Principal at Novartis Venture Fund based in Cambridge, Massachusetts from January 2018 until July 2019. Ms. Audet currently serves on the board of directors of Mestag Therapeutics Limited. Ms. Audet received an M.B.A., with distinction, from Harvard Business School and her M.Sc in physics from EPFL (Lausanne, Swiss Federal Institute of Technology).

We believe that Ms. Audet's extensive experience investing in life science companies and her managerial experience provider her the qualifications and skills to serve on the Board of Directors.

Dr. Louis Lange. Louis Lange, M.D., Ph.D., was appointed to the Board of Directors in November 2022. Dr. Lange previously served on the NewAmsterdam Pharma board from 2021 to November 2022. Dr. Lange previously served as the chief of cardiology and a professor of medicine at the Washington University School of Medicine and was one of the early academicians in molecular cardiology. Dr. Lange founded and served as the chief executive officer and chairman of CV Therapeutics, Inc. (Nasdaq: CVTX) from 1990 until 2019, and as a senior advisor to Gilead Sciences, Inc. from 2009 until 2019, following its acquisition of CV Therapeutics. Dr. Lange currently serves as a general partner with Asset Management Ventures. Dr. Lange also serves on the board of directors of Stealth Biotherapeutics Corp. (private), BioPlus Acquisition Corp. (Nasdaq:BIOS), Amygdala Neurosciences, Inc. and Recardia, Inc. Dr. Lange previously served on the board of directors of Audentes Therapeutics, Inc. (sold to Astellas Pharma Inc.) and Epiphany Tech Acquisition Corp., (Nasdaq: EPHY). Dr. Lange has a Bachelor's degree from the University of Rochester, an M.D. from Harvard University and a Ph.D. in Biological Chemistry, also from Harvard University.

We believe that Dr. Lange's board experience, medical background and experience as a public company officer, provide Dr. Lange with the qualifications and skills to serve on the Board of Directors.

Sander Slootweg. Sander Slootweg was appointed to the Board of Directors in November 2022. Mr. Slootweg previously served on the NewAmsterdam Pharma board from 2020 until November 2022. Mr. Slootweg co-founded Forbion and has served as managing partner since 2006. Mr. Slootweg currently serves on the boards of several of Forbion's portfolio companies including Replimune Group Inc., NorthSea Therapeutics B.V., Azafaros B.V., Xention, Oxyrane Belgium NV and Forbion European Acquisition Corporation (Nasdaq: FRBN). Mr. Slootweg was responsible for several substantial exits: Forbion's major position in Argenx SE (Nasdaq: ARGX), Dezima's acquisition by Amgen in 2015 for up to \$1.55 billion and the sale of Biovex Group, Inc. to Amgen in 2011 for up to \$1 billion. Mr. Slootweg has previously served on the boards of Pulmagen Therapeutics, Fovea Pharmaceuticals SA (sold to Sanofi-aventis in 2009), uniQure N.V. (IPO on Nasdaq in 2014), Argenta Limited (sold to Galapagos NV in 2010), Alantos Pharmaceuticals, Inc. (sold to Amgen in 2007), Impella CardioSystems AG (sold to Abiomed Inc. in 2005), Pieris Pharmaceuticals, Inc. (IPO on Nasdaq in 2015). Before co-founding Forbion, Mr. Slootweg was an investment director at ABN AMRO Capital Life Sciences. Mr. Slootweg holds degrees in business and financial economics from the Free University of Amsterdam and business administration from Nijenrode University, The Netherlands.

We believe that Mr. Slootweg’s experience investing in and serving on multiple boards of life science companies, provide Mr. Slootweg with the qualifications and skills to serve on the Board of Directors.

Dr. Nicholas Downing. Nicholas Downing, M.D., was appointed to the Board of Directors in November 2022. Dr. Downing joined Bain Capital Life Sciences in 2018 where he currently serves as a Partner. Prior to joining Bain Capital, Dr. Downing was a resident physician at the Brigham and Women’s Hospital in Boston from 2015 until 2018, where he cared for patients on the inpatient medical service and in the outpatient clinic. Throughout his medical career, Dr. Downing has been an active health policy researcher and is the author of over 40 articles in the peer-reviewed scientific literature. Prior to his medical career, Dr. Downing was a consultant at McKinsey and Company where he worked with clients in the pharmaceutical, hospital and financial services industries on a wide range of strategic problems. Dr. Downing also serves as a director on the board of Kestra Medical Technologies, Ltd., Cardurion Pharmaceuticals, Inc. and River Renal Companies. Dr. Downing graduated from Harvard College magna cum laude with a degree in chemistry. He received an M.D. cum laude from Yale University School of Medicine.

We believe that Dr. Downing’s medical experience, as well as his experience investing and serving on the boards of life science companies provide Dr. Downing with the qualifications and skills to serve on the Board of Directors.

John W. Smither. John Smither was appointed as temporary non-executive director in January 2023. Mr. Smither has been appointed by the Board of Directors as temporary non-executive director in fulfilment of a vacant position within the Board of Directors until his proposed appointment by the General Meeting at the next annual General Meeting. Mr. Smither previously served as the Chief Financial Officer of Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) from May 2019 until March 2021 and the Chief Financial Officer of Sienna Biopharmaceuticals, Inc. (Nasdaq: SNNA) from April 2018 until March 2019. Mr. Smither also served as the interim Chief Financial Officer at Kite Pharma (a Gilead Sciences, Inc. company) from October 2017 until April 2018 during its integration with Gilead. Mr. Smither currently serves on the board of directors and audit committee chair of eFFECTOR Therapeutics, Inc. (Nasdaq: EFTR) and Applied Molecular Transport, Inc. (Nasdaq: AMTI). Mr. Smither also serves as a member of the nomination and corporate governance committee and the compensation committee of eFFECTOR Therapeutics and Applied Molecular Transport, respectively. Mr. Smither previously served on the board of directors of Achaogen, Inc. and Principia Biopharma Inc. Mr. Smither also has 15 years’ experience as a practicing CPA (inactive), including time spent as an audit partner with Ernst & Young LLP.

We believe that Mr. Smither’s experience as the Chief Financial Officer for a number of public companies and his experience serving on the board of directors and audit committees of other public life science companies provide Mr. Smither with the qualifications and skills to serve on the Board of Directors.

Janneke van der Kamp. We plan to appoint Janneke van der Kamp as a temporary non-executive director as of April 1, 2023. She has been appointed by the Board of Directors as temporary non-executive director in fulfilment of a vacant position within the Board of Directors until her proposed appointment by the General Meeting at the next annual General Meeting. Ms. van der Kamp currently serves as the Chief Commercial Officer of Grünenthal and previously spent two decades in roles of increasing responsibility at Novartis, ultimately serving on the Pharma Executive Committee as Global Head of Product & Portfolio Strategy and then Head of Pharma Region Europe from January 2017 until January 2022. While at Novartis, Ms. van der Kamp supported the launch of Novartis’ key cardiovascular disease medicines, as well as the company’s efforts in immunology, dermatology, neuroscience, ophthalmology, and respiratory disease. Ms. van der Kamp received her M.S. in chemistry from Utrecht University and M.B.A. from INSEAD.

We believe that Ms. van der Kamp’s operational experience in the pharmaceutical industry and business development experience provide Ms. van der Kamp that qualifications and skills to serve on the Board of Directors.

Executive Officers

The following table lists the names, ages and positions of our current executive officers as of the date hereof.

Name	Age	Position
Michael Davidson, M.D.	66	Chief Executive Officer
Marc Ditmarsch, M.D.	57	Chief Development Officer
John Kastelein, M.D.	69	Chief Scientific Officer
Douglas Kling	49	Chief Operating Officer
Louise Kooij	47	Interim Chief Financial Officer

Dr. Michael Davidson. Dr. Davidson’s biography is included above under “—Board of Directors.”

Dr. Marc Ditmarsch. Marc Ditmarsch, M.D., joined NewAmsterdam Pharma in January 2020 as its Vice President of Clinical & Operations and was promoted to Chief Development Officer in August 2022. Prior to joining NewAmsterdam Pharma, Dr. Ditmarsch

served as an independent consultant for clinical development and operations at Gadeta Biotechnology from 2019 until 2020. From 2016 until 2019, Dr. Ditmarsch served as a country medical director at AstraZeneca and as global product vice president in the global medicines development organization from 2014 until 2016. Dr. Ditmarsch previously worked at F. Hoffmann-La Roche AG and as a vascular and emergency medicine resident surgeon. Dr. Ditmarsch received his M.D. from the faculty of medicine at the Free University in Amsterdam.

Dr. John Kastelein. Dr. Kastelein’s biography is included above under “—Board of Directors.”

Douglas Kling. Douglas Kling joined NewAmsterdam Pharma 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 Matina 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 was appointed as the Company’s Interim Chief Financial Officer in March 2023. Ms. 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. Ms. Kooij previously spent 14 years working in various finance roles at Genzyme Europe B.V., a multinational biotechnology company. 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. From January 2016 to April 2018, Ms. Kooij led Genzyme’s business operations team in Europe and from April 2018 until May 2020, served as the head of Genzyme’s rare disease unit in central and eastern Europe. Ms. Kooij received a master’s degree from Nyenrode Business University and her auditing degree from Hogeschool Markus Verbeek.

Family Relationships

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

Arrangements and Understandings

Two of our non-executive directors were designated by FLAC, and one executive director and four non-executive directors were designated by NewAmsterdam Pharma pursuant to the terms of the Business Combination Agreement.

B. COMPENSATION

Historical Compensation of Our Executive Officers

The amount of compensation, including benefits in kind, accrued or paid to our executive officers (other than Drs. Davidson and Kastelein) with respect to the year ended December 31, 2022 is described in the table below. We are providing disclosure on an aggregate basis, as disclosure of compensation on an individual basis is not required in our home country and is not otherwise publicly disclosed by us.

All executive officers	(in Euros ‘000)⁽¹⁾
Base Compensation ⁽²⁾	477
Bonuses ⁽³⁾	249
Management Fees ⁽⁴⁾	370
Options Granted in 2022 ⁽⁵⁾	830
Total Compensation	1,926

(1) Amounts paid in U.S. dollars have been converted to Euros in accordance with IAS 21—the Effects of Changes in Foreign Exchange Rates.

(2) Base compensation represents the cash compensation paid annually to NewAmsterdam Pharma’s executive officers.

(3) Bonus amounts are fixed per each executive officer’s employment agreement.

(4) Management fees consist of discretionary cash bonuses paid to executive officers (other than our executive officers serving as directors) serving in a consulting capacity.

(5) 1,448,273 options to purchase Ordinary Shares were granted to executive officers pursuant to NewAmsterdam Pharma’s long-term incentive plan and each have an expiration date of no later ten years from the date of grant and an exercise price of \$10.00 per option share. The aggregate fair value of the options that is set forth in the table above was determined pursuant to the regulations of IFRS 2 “Share-based Payments.”

The amount set aside or accrued by us to provide pension, retirement or similar benefits to members of senior management amounted to a total of €11 thousand in the year ended December 31, 2022.

Compensation of our Directors

The amount of compensation, including benefits in kind, accrued or paid to our directors with respect to the year ended December 31, 2022 is described in the table below.

(in Euros '000) ⁽¹⁾	Louis Lange	Michael Davidson	John Kastelein
Cash Compensation	61	458	342
Options Granted in 2022 ⁽²⁾	62	1,303	597
Bonuses	—	173	137
Total Compensation	123	1,934	1,076

(1) Amounts paid in U.S. dollars have been converted to Euros in accordance with IAS 21—the Effects of Changes in Foreign Exchange Rates.

(2) The following options were granted to directors (including Drs. Davidson and Kastelein) pursuant to NewAmsterdam Pharma's long-term incentive plan: 3,507,099 options for non-voting ordinary shares, each with an expiration date of no later ten years from the date of grant and an exercise price of \$10.00 per option share. The aggregate fair value of the options that is set forth in the table above was determined pursuant to the regulations of IFRS 2 "Share-based Payments."

There were no amounts set aside or accrued by us to provide pension, retirement or similar benefits to members of the Board of Directors in the year ended December 31, 2022.

Director and Executive Officer Award Grants

On January 1, 2023, we granted (i) options to purchase an aggregate of 720,949 Ordinary Shares to certain of our executive officers (excluding awards granted to executive officers who also serve as directors) and (ii) options to purchase Ordinary Shares to certain of our directors as shown in the table below. Such options each have an expiration date of ten years from the date of grant and an exercise price of \$10.90.

Director	Options Granted
Michael Davidson	1,021,485
John Kastelein	477,347
Louis Lange	57,583

Director and Executive Officer Compensation

Dutch law does not provide for limitations with respect to the aggregate annual compensation paid to our directors or executive officers, provided that compensation paid to our directors must be consistent with our compensation policy. Such compensation policy was adopted by the General Meeting prior to the closing of the Business Combination. Changes to such 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. A proposal with respect to compensation schemes in the form of Ordinary Shares or rights to Ordinary Shares in which directors may participate (such as the LTIP) is also subject to approval by the General Meeting by simple majority of votes cast. Such a proposal must set out at least the maximum number of shares or rights to subscribe for shares to be granted to our directors and the criteria for granting or amendment.

Directors Service Agreements

We entered into services agreements with all of our directors which regulate their services as our directors. These services agreements 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.

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.

LTIP

We have established our long-term incentive plan (the “LTIP”), pursuant to which we may grant options, restricted stock, restricted stock units, share appreciation rights and other equity and equity-based awards. The total number of Ordinary Shares underlying awards granted pursuant to the LTIP (other than awards granted as replacement awards in connection with a merger or business combination) will not exceed 9,571,101; provided that the number of Ordinary Shares initially reserved for grant under the LTIP will increase annually on January 1 of each calendar year, including the first increase on January 1, 2023, 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 its compensation committee. We may grant awards under the LTIP to our directors, employees, consultants or other advisors. The Board of Directors (or its compensation committee) may condition awards under the LTIP upon the achievement or satisfaction of performance criteria and will determine the vesting conditions for awards under the LTIP. The LTIP includes provisions for good leavers and bad leavers as well as for a change in control.

Rollover Option Plan

We also established a rollover option plan (the “Rollover Plan”), pursuant to which we assumed the outstanding NewAmsterdam Pharma Options of certain NewAmsterdam Pharma optionholders 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 awards granted under the Rollover Plan that are forfeited, canceled or otherwise terminated shall become available for issuance under the LTIP.

The Rollover Plan is administered by the Board of Directors and its compensation committee. The options subject to the Rollover Plan will continue on the same terms as the NewAmsterdam Pharma Options for which they were exchanged. The Rollover Plan includes provisions applicable in the event of a change of control.

Supplementary LTIP

On December 15, 2022, we established our supplementary long-term incentive plan (the “Supplementary LTIP”), pursuant to which we may grant options, restricted stock, restricted stock 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 pursuant to 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 its compensation committee. The awards issued pursuant to the Supplementary LTIP will have terms substantially similar to those issued pursuant to the LTIP. The Supplementary LTIP includes provisions applicable in the event of a change of control.

C. BOARD PRACTICES

Board Structure, Directors and Executive Officers

Board Structure

We are a Dutch public limited liability company (*naamloze vennootschap*) with a single-tier board structure. The Board of Directors currently consists of one executive director and seven non-executive directors, of which one has been appointed as a temporary non-executive director by the Board of Directors until their proposed appointment as a non-executive director by the General Meeting. The Board of Directors has appointed Janneke van der Kamp as a temporary non-executive director effective April 1, 2023. There are no family relationships among any of our directors.

Board of Directors

The Board of Directors may consist of up to nine members, comprised of one executive director and eight non-executive directors. Effective April 1, 2023, the Board of Directors will consist of nine members, of which two non-executive directors were initially designated by FLAC and one executive director and four non-executive directors were initially designated by NewAmsterdam Pharma pursuant to the terms of the Business Combination Agreement. Each of our initial directors will hold office for the term set by the General Meeting, except in the case of his or her earlier death, resignation or dismissal. Our directors do not have a retirement age requirement under the Articles of Association.

Our directors will be (re-)appointed by the General Meeting upon a binding nomination by the Board of Directors. The General Meeting may at all times overrule a binding nomination by a resolution adopted by a majority of at least two thirds of the

votes cast, provided such majority represents more than half of the issued share capital. If the General Meeting overrules a binding nomination, the Board of Directors will make a new nomination.

The DCGC provides the following best practice recommendations on the terms for tenure of directors:

- executive directors should be appointed for a maximum period of four years, without limiting the number of consecutive terms they may serve and non-executive directors should be appointed for two consecutive periods of no more than four years.
- Thereafter, non-executive directors may be reappointed for a maximum of two consecutive periods of no more than two years, provided that the reasons for any reappointment after an eight-year term of office should be disclosed in our statutory annual report.

The executive director on the Board of Directors was appointed for an initial term of three years. The initial non-executive directors on the Board of Directors were appointed with staggered terms of up to three years. The initial directors were selected pursuant to the Business Combination Agreement.

The General Meeting may at any time suspend or dismiss a director. The General Meeting may only adopt a resolution to suspend or dismiss a director by a majority of at least two thirds of the votes cast, provided such majority represents more than half of the issued share capital, unless the resolution is adopted at the proposal of the Board of Directors, in which latter case the resolution may be adopted by a simple majority of the votes cast.

Director and Officer Qualifications

We have not formally established any specific, minimum qualifications that must be met by each of our directors and other officers. However, we generally expect to evaluate the following qualities: educational background, diversity of professional experience, knowledge of our business, integrity, professional reputation, independence, wisdom and the ability to represent the best interests of our stakeholders.

The nomination and corporate governance committee is responsible for policies regarding director qualification requirements and the process for identifying and evaluating director candidates for adoption by the Board of Directors.

Committees of the Board of Directors

The Board of Directors has established three standing committees: the Audit Committee, Compensation Committee and Nomination and Corporate Governance Committee.

Audit Committee

The audit committee consists of Louis Lange, John W. Smither and Juliette Audet. John W. Smither serves as chairperson of the audit committee. The audit committee assists the Board of Directors in overseeing the Company's accounting and financial reporting processes, the engagement of its independent auditor, and the audits of its financial statements. The Board of Directors has determined that Louis Lange qualifies as an "audit committee financial expert," as such term is defined in the rules of the SEC.

We are relying on the phase-in rules of the SEC and Nasdaq with respect to the independence of our audit committee. These rules require that all members of our audit committee must meet the independence standard for audit committee membership within one year of such effectiveness. The audit committee is governed by a charter that complies with applicable rules of Nasdaq, which is posted on our website.

Compensation Committee

The compensation committee consists of Louis Lange and Nicholas Downing. Louis Lange serves as chairperson of the compensation committee. The compensation committee assists the Board of Directors in determining compensation for our directors and executive officers.

The compensation committee is governed by a charter that is posted on our website.

Nomination and Corporate Governance Committee

The nomination and corporate governance committee consists of Sander Sloomweg, Nicholas Downing and Louis Lange. Sander Sloomweg serves as chairperson of the nomination and corporate governance committee. The nomination and corporate governance committee assists the Board of Directors in identifying individuals qualified to become our directors consistent with criteria we established and in developing our code of business conduct and ethics.

The nomination and corporate governance committee is governed by a charter that is posted on our website.

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. This code applies to all of our employees, officers and directors. Our code of business conduct and ethics is available on our website.

Dividend Policy

We have never declared or paid any cash dividends on our Ordinary 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. The Board of Directors may only pay dividends and other distributions from our reserves to the extent our shareholders' equity (*eigen vermogen*) exceeds the sum of the Company's paid-in and called-up share capital plus the reserves we must maintain under Dutch law or the Articles of Association and (if it concerns a distribution of profits) after adoption of our statutory annual accounts by 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 our reserves will be at the discretion of the Board of Directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors the Board of Directors deems relevant. For more information regarding our dividend policy, see "Item 8. Financial Information—A. Consolidated Statements and Other Financial Information—Dividends and Dividend Policy" below.

D. EMPLOYEES

As of December 31, 2022, we had 17 full-time employees, consisting of clinical, research and development, business development, regulatory, finance and operational personnel, who are employed through our wholly owned U.S. subsidiary, NewAmsterdam Pharma Corporation. None of our employees are subject to a collective bargaining agreement. We consider our relationship with our employees to be good. We have also engaged consultants to assist with our clinical development and regulatory obligations. Our Dutch wholly owned subsidiary, NewAmsterdam Pharma B.V., engages a total of nine independent contractors. These independent contractors provide a diverse array of services, which includes assisting with our clinical development and regulatory obligations.

E. SHARE OWNERSHIP

See "Item 7. Major Shareholders and Related Party Transactions—A. Major Shareholders."

F. DISCLOSURE OF A REGISTRANT'S ACTION TO RECOVER ERRONEOUSLY AWARDED COMPENSATION

We maintain a Compensation Clawback Policy (the "Clawback Policy") in compliance with the SEC's and Nasdaq Stock Market, LLC's final rules. The Clawback Policy requires the repayment of certain erroneously awarded incentive-based compensation paid to any current or former executive officer, including our named executive officers, in connection with a restatement of financial statements if such compensation exceeded the amount that such executive officers otherwise would have received had it been determined based on the restated financial statements. Our compensation committee assessed the applicability of the Clawback Policy in light of the restatement of the Affected Financial Statements in order to correct the error contained therein. No Incentive-Based Compensation (as defined in the Clawback Policy) was paid during the requisite look-back period and as a result, the Company concluded that no compensation is required to be recouped as a result of the restatement of the Affected Financial Statements.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. MAJOR SHAREHOLDERS

The following table sets forth information regarding the actual beneficial ownership of Ordinary Shares as of March 22, 2023, 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 81,766,785 Ordinary Shares issued and outstanding, as of March 22, 2023. 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.

Beneficial Owner	Number of Ordinary Shares	Percentage of All Ordinary Shares
Executive Officers and Directors		
Juliette Audet ⁽¹⁾	6,635,391	8.12 %
Michael Davidson, M.D. ⁽²⁾	1,783,761	2.18 %
Nicholas Downing, M.D. ⁽³⁾	—	—
John Kastelein, M.D., Ph.D, FESC ⁽⁴⁾	1,595,446	1.95 %
Louis Lange, M.D., Ph.D. ⁽⁵⁾	52,700	*
Sander Slootweg ⁽⁶⁾	18,991,588	23.23 %
James N. Topper, M.D., Ph.D. ⁽⁷⁾	9,801,333	11.99 %
Marc Ditmarsch, M.D. ⁽⁸⁾	284,176	*
Douglas Kling ⁽⁹⁾	369,494	*
Louise Kooij ⁽¹⁰⁾	213,608	*
John W. Smither	—	—
Janneke van der Kamp ⁽¹¹⁾	—	—
All executive officers and directors as a group (12 persons)	39,727,497	52.05 %
Beneficial Owner	Number of Ordinary Shares	Percentage of All Ordinary Shares
Other 5% Shareholders		
Morningside Venture Investments Limited ⁽¹²⁾	5,065,846	6.20 %
Entities affiliated with Forbion ⁽¹³⁾	18,991,588	23.23 %
Saga Investments Coöperatief U.A. ⁽¹⁴⁾	4,910,000	6.00 %
Stichting Administratiekantoor NewAmsterdam Pharma ⁽¹⁵⁾	5,326,818	6.51 %
Frazier Lifesciences Sponsor LLC and affiliates ⁽¹⁶⁾	9,801,333	11.99 %
Entities affiliated with Bain Capital Life Sciences Investors, LLC ⁽¹⁷⁾	8,400,000	10.27 %
RA Capital Healthcare Fund, L.P. ⁽¹⁸⁾	4,333,333	5.30 %

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

- (1) Consists of (i) 6,635,391 Ordinary Shares held by Forbion Capital Fund IV Coöperatief U.A. (“Forbion IV”) inclusive of 1,500,000 Ordinary Shares subscribed for in connection with the PIPE Financing. The address for Forbion IV is Gooimeer 2-35, 1411 DC Naarden, the Netherlands. Forbion IV Management B.V. (“Forbion IV Management”), the director of Forbion IV, may be deemed to have voting and dispositive power over the Ordinary Shares held by Forbion IV. Investment decisions with respect to the Ordinary Shares held by Forbion IV can be made by its investment committee which may delegate such powers to the authorized representatives of Forbion IV Management. Messrs. Slootweg, van Osch, Mulder, van Houten, van Deventer, Reithinger, Kersten and Boorsma are partners of Forbion IV Management, which acts as the investment advisor to the director of Forbion IV. Ms. Audet and Mr. Slootweg are members of the investment committee of Forbion IV. Forbion IV Management disclaims beneficial ownership of the shares, except to the extent of their pecuniary interest therein.
- (2) Consists of (i) 189,784 Ordinary Shares, (ii) options to purchase 985,198 Ordinary Shares, exercisable within 60 days of March 22, 2023 and (iii) 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 (iii) 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.
- (3) 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.

- (4) Consists of (i) 268,472 Ordinary Shares held by Futurum B.V. (“Futurum”) through NAP PoolCo B.V. (“PoolCo”), (ii) 228,881 Ordinary Shares underlying depositary receipts issued by STAK NAP (as defined below) which are held by Futurum through PoolCo, (iii) options to purchase 976,624 Ordinary Shares held by Futurum through PoolCo and (iv) options to purchase 121,470 Ordinary Shares held by Dr. Kastelein directly, each exercisable within 60 days of March 22, 2023. STAK NAP has sole voting and investment power over the securities described in (ii) underlying the depositary receipts and are presented here because the depositary receipts can be cancelled by the board of directors of STAK NAP at any time as a consequence of which the shareholder will become the beneficial owner of the securities underlying such depositary receipts.
- (5) Consists of options to purchase 52,700 Ordinary Shares, exercisable within 60 days of March 22, 2023.
- (6) Consists of the Ordinary Shares described in Note 13. Mr. Slootweg disclaims beneficial ownership of the shares referenced in Note 13, except to the extent of his pecuniary interest therein, if any.
- (7) Consists of the shares described in Note 16. Dr. Topper disclaims beneficial ownership of the shares referenced in Note 16, except to the extent of his pecuniary interest therein, if any.
- (8) Consists of options to purchase 239,746 Ordinary Shares held by Diomedea Medical B.V. through PoolCo and options to purchase 44,430 Ordinary Shares held by Dr. Ditmarsch directly, each exercisable within 60 days of March 22, 2023.
- (9) Consists of options to purchase 369,494 Ordinary Shares, exercisable within 60 days of March 22, 2023.
- (10) Consists of options to purchase 159,854 Ordinary Shares held by LouFré Management B.V. through PoolCo and options to purchase 53,754 Ordinary Shares held by Ms. Kooij directly, each exercisable within 60 days of March 22, 2023.
- (11) Ms. van der Kamp’s appointment as a temporary non-executive director will be effective April 1, 2023.
- (12) Consists of 5,065,846 Ordinary Shares directly and beneficially held by Morningside Venture Investments Limited (“Morningside”), inclusive of 500,000 Ordinary Shares subscribed for in connection with the PIPE Financing. Frances Anne Elizabeth Richard, Jill Marie Franklin, Peter Stuart Allenby Edwards and Cheung Ka Ho are the directors of Morningside and share voting and dispositive power with respect to the securities held by Morningside. Each of Ms. Richard, Ms. Franklin, Mr. Edwards and Mr. Ho disclaim beneficial ownership of the Ordinary Shares held by Morningside except to the extent of their pecuniary interest therein. Morningside is ultimately wholly beneficially owned by a trust over which Adriel Wenbwo Chan and Wong Yuk Lan share authority to remove the trustee. The address of Morningside is c/o THC Management Services S.A.M., 2nd Floor, Le Prince de Galles, 3-5 Avenue des Citronniers, MC 98000, Monaco. The information herein is based solely on the Schedule 13G filed by Morningside, Ms. Richard, Ms. Franklin, Mr. Edwards and Mr. Ho on December 2, 2022.
- (13) Consists of (i) 6,635,391 Ordinary Shares held by Forbion IV, inclusive of 1,500,000 Ordinary Shares subscribed for in connection with the PIPE Financing, (ii) 4,543,897 Ordinary Shares held by Forbion Growth Opportunities Fund I Coöperatief U.A. (“Forbion Growth”), inclusive of 1,500,000 Ordinary Shares subscribed for in connection with the PIPE Financing and (iii) 7,812,300 Ordinary Shares held by Forbion Capital Fund II Coöperatief U.A. (“Forbion II”) through PoolCo, including 2,828,380 Ordinary Shares underlying depositary receipts issued by STAK NAP. The address for the Forbion entities is Gooimeer 2-35, 1411 DC Naarden, the Netherlands.

Forbion IV Management, the director of Forbion IV, may be deemed to have voting and dispositive power over the Ordinary Shares held by Forbion IV. Investment decisions with respect to the Ordinary Shares held by Forbion IV can be 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 acts as the investment advisor to the director of Forbion IV. Mr. Slootweg is a member of the board of directors and is a partner of Forbion IV Management and a member of the investment committee of Forbion IV. Forbion IV Management disclaims beneficial ownership of the Ordinary Shares, except to the extent of their pecuniary interest therein.

Forbion Growth Management B.V. (“Growth Management”), the director of Forbion Growth, may be deemed to have voting and dispositive power over the Ordinary Shares held by Forbion Growth. Investment decisions with respect to the Ordinary Shares held by Forbion Growth can be 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 and Boorsma are partners of Growth Management, which acts as the investment advisor to the director of Forbion Growth. Mr. Slootweg is a member of the board of directors and is a partner of Growth Management and a member of the investment committee of Forbion Growth. Growth Management disclaims beneficial ownership of the Ordinary Shares, except to the extent of their pecuniary interest therein.

Forbion II Management B.V. (“Forbion II Management”), the director of Forbion II, may be deemed to have voting and dispositive power over the Ordinary Shares held by Forbion II. Investment decisions with respect to the Ordinary Shares held by Forbion II can be made by its investment committee which may delegate such powers to the authorized representatives of Forbion II Management. Mssrs. Slootweg, van Osch, Mulder, van Deventer, Reithinger, and Bergstein are (ex)partners of Forbion II Management, which may act as the investment advisor to the director of Forbion II. Mr. Slootweg is a member of the board of directors and is a partner of Forbion II Management and a member of the investment committee of Forbion II.

Forbion II Management and its partners disclaims beneficial ownership of the Ordinary Shares, except to the extent of their pecuniary interest therein. 4,983,920 Ordinary Shares are held by Forbion II through PoolCo.

BioGeneration II Management B.V. (“BGM II”) is the director of (1) BioGeneration Ventures II B.V., which, through PoolCo, holds 415,873 Ordinary Shares underlying depositary receipts issued by STAK NAP, (2) BGV II Coöperatief U.A. which, through PoolCo, holds 2,269 Ordinary Shares underlying depositary receipts issued by STAK NAP, and (3) BioGeneration II Co-Invest B.V. which through PoolCo holds 11,958 Ordinary Shares underlying depositary receipts issued by STAK NAP. BGM II is an indirect joint venture between the BGM investment team and the partners of Forbion II Management. Mr. Slootweg is a member of the board of directors and is a partner of Forbion II and a member of the investment committee of BGM II. BGM II disclaims beneficial ownership of the Ordinary Shares, except to the extent of their pecuniary interest therein.

- (14) Amgen Singapore Manufacturing Pte. Ltd. (“Amgen Singapore”) is the sole shareholder of Saga Investments Coöperatief U.A. Amgen Technology, Limited (“Amgen Technology”) is the sole shareholder of Amgen Singapore and Onyx Pharmaceuticals, Inc. (“Onyx”) and Amgen Inc. (“Amgen”) are the shareholders of Amgen Technology. As a result, Amgen Singapore, Amgen Technology Onyx and Amgen may each be deemed to share beneficial ownership of the Ordinary Shares held of record by Saga Investments Coöperatief U.A. The business address is Minervum 7061, 4817 ZK Breda, The Netherlands. The information herein is based solely on the Schedule 13G filed by the Saga Investments Coöperatief U.A., Amgen Singapore, Amgen Technology, Onyx and Amgen on December 2, 2022.
- (15) Stichting Administratiekantoor NewAmsterdam Pharma (“STAK NAP”) is a Dutch foundation which holds Ordinary Shares on behalf of the holders of depositary receipts issued by STAK NAP. STAK NAP has issued depositary receipts to the participants with each depositary receipt representing the relevant underlying security. Pursuant to STAK NAP’s governing documents, STAK NAP, through its board, has the power to exercise all rights associated with the Ordinary Shares underlying the depositary receipts. As a result, STAK NAP may be deemed to have voting power over such securities. 2,828,380 Ordinary Shares owned by Forbion II are underlying the depositary receipts held through STAK NAP. Forbion International Management B.V. (“FIM”) is the sole director of STAK NAP and may be deemed to have voting and dispositive power of the Ordinary Shares held by STAK NAP. Mssrs. Slootweg, Van Osch, Reithinger, Mulder, Van Houten and Boorsma are the directors of FIM. FIM and its directors disclaim beneficial ownership of the Ordinary Shares.
- (16) 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 is (i) 1,000,000 Ordinary Shares and Warrants to purchase 333,333 Ordinary Shares held by FLS X, (ii) 2,000,000 Ordinary Shares subscribed for by FLS X in connection with the PIPE Financing, (iii) 500,000 Ordinary Shares subscribed for by Frazier Life Sciences XI, L.P. (“FLS XI”) in connection with the PIPE Financing, (iv) 1,000,000 Ordinary Shares subscribed for by Frazier Life Sciences Public Fund, L.P. (“FLSPF”), in connection with the PIPE Financing and (v) 1,000,000 Ordinary Shares subscribed for by Frazier Life Sciences Overage Fund, L.P. (FLSOF”) in connection with the PIPE Financing. 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, and Dan Estes 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 solely on the Schedule 13D filed by the 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 2, 2022. The address of these holders is Two Union Square, 601 Union St., Suite 3200, Seattle, WA 98101.

- (17) Consists of (i) 4,000,000 Ordinary Shares held by BCLS II Investco, LP (“BCLS II Investco”) subscribed for in connection with the PIPE Financing, (ii) 4,000,000 Ordinary Shares held by BCLS Fund III Investments, LP (“BCLS Fund III”) subscribed for in connection with the PIPE Financing, (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”) and (iv) 32,571 Ordinary Shares and Warrants to purchase 10,857 Ordinary Shares held by BCIP Life Sciences Associates, LP (“BCIPLS”) and, together with BCLS II Investco, BCLS Fund III and BCLS Fund II, the “Bain Capital Life Sciences Entities”). 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 manager 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 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 filed by the Bain Capital Life Sciences Entities on December 2, 2022.
- (18) Consists of 4,000,000 Ordinary Shares and Warrants to purchase 333,333 Ordinary Shares held 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 filed by RACHF, RA Capital, Mr. Kolchinsky and Mr. Shah on December 2, 2022.

Holdings by U.S. Shareholders

We estimate that as of March 22, 2023, approximately 49% of our outstanding ordinary shares are held by 52 U.S. record holders.

B. RELATED PARTY TRANSACTIONS

Our Related Party Transactions

Since January 1, 2022, we have engaged in the following transactions with our directors, executive officers or holders of more than 10% of our securities.

Business Combination

On November 22, 2022, we consummated our previously announced business combination pursuant to the Business Combination Agreement, by and among the Company, FLAC, NewAmsterdam Pharma, and 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:

- The shareholders of NewAmsterdam Pharma (including Drs. Davidson and Kastelein and 10% shareholders) effected the Exchange;
- Immediately after giving effect to the Exchange, our legal form was converted from a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) to a public limited liability company (*naamloze vennootschap*);
- After giving effect to the Exchange, we effected the Merger, with FLAC surviving as our wholly owned subsidiary;
- 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 us against the issuance of a corresponding Ordinary Share;

- Immediately following the Merger, each outstanding warrant to purchase a FLAC Class A Ordinary Share became a warrant to purchase one Ordinary Share, on the same contractual terms;
- Each NewAmsterdam Pharma Option, to the extent invested, will continue to vest in accordance with its applicable terms, and at the time of the Exchange, such NewAmsterdam Pharma Option became options to purchase, and will when exercised be settled in Ordinary Shares; and
- On the day following the Closing Date, FLAC changed its jurisdiction of incorporation by deregistering as a Cayman Islands exempted company and domesticated as a corporation incorporated under the laws of the State of Delaware.

Upon the closing of the Business Combination, we became the direct parent of NewAmsterdam Pharma.

PIPE Financing

Affiliates of certain of our directors and certain of our major shareholders participated in the PIPE Financing.

Forbion Growth Opportunities Fund I Coöperatief U.A., Forbion Capital Fund IV Coöperatief U.A. and Morningside Venture Investments Limited, each of whom was an existing investor in NewAmsterdam Pharma, have purchased an aggregate of 3,500,000 Ordinary Shares (for an aggregate purchase price of \$35 million) in the PIPE Financing. This transaction was on the same terms as the other investors who purchased shares in the PIPE Financing pursuant to certain subscription agreements dated July 25, 2022. The 3,500,000 Ordinary Shares received by Forbion Growth Opportunities Fund I Coöperatief U.A., Forbion Capital Fund IV Coöperatief U.A. and Morningside Venture Investments Limited received registration rights pursuant to the terms of the Subscription Agreement.

Frazier Life Sciences X, L.P., Frazier Life Sciences XI, L.P., Frazier Life Sciences Public Fund, L.P. and Frazier Life Sciences Overage Fund, L.P. purchased 4,500,000 Ordinary Shares (for an aggregate purchase price of \$45 million) in the PIPE Financing. The transaction was on the same terms as the other investors who purchased shares in the PIPE Financing pursuant to certain subscription agreements dated July 25, 2022. Frazier Life Sciences X, L.P. is the sole member of the Sponsor and Jamie Topper has voting discretion in each of Frazier Life Sciences X, L.P., Frazier Life Sciences Overage Fund, L.P., Frazier Life Sciences XI, L.P. and Frazer Life Sciences Public Fund, L.P. Further, Jamie Topper has a pecuniary interest in the general partner of each of the foregoing funds. See the section “*Item 5. Operating and Financial Review and Prospects—B. Liquidity and Capital Resources—Sources of Liquidity*” for more information about the PIPE Financing.

Each of these related parties purchased the PIPE Shares at \$10.00 per share which has been less than the price of our Ordinary Shares in the past and may be below the price of our Ordinary Shares in the future. If the trading price of our Ordinary Shares remains higher than the price paid for the PIPE Shares, the related parties who purchased PIPE Shares may experience a positive rate of return while shareholders who purchase our Ordinary Shares in the open market may not.

Company Support Agreement

In connection with the execution of the Business Combination Agreement, the Company, NewAmsterdam Pharma, FLAC, Merger Sub, and certain existing shareholders of NewAmsterdam Pharma (which shareholders only include directors, executive officers and shareholders with voting securities in NewAmsterdam Pharma representing 5% or more of all such voting securities) entered into the Company Support Agreement pursuant to which, among other things, each such existing shareholder of NewAmsterdam Pharma (a) granted or will grant, as applicable, NewAmsterdam Pharma (or a designee thereof) with a power of attorney permitting and directing NewAmsterdam Pharma to execute on behalf of such shareholder a Dutch deed of issue to effect the Exchange with respect to the shares of NewAmsterdam Pharma held by such shareholder, (b) undertook or will undertake, as applicable, vis-à-vis NewAmsterdam Pharma, the Company, FLAC and each other existing shareholder of NewAmsterdam Pharma to take all necessary or desirable actions in connection with the transactions set forth in the Business Combination Agreement, (c) agreed to vote in favor of the approval of the Business Combination Agreement, the Exchange and any other matters necessary or reasonably requested by NewAmsterdam Pharma to consummate the transactions contemplated in the Business Combination Agreement, and (d) agreed to certain customary covenants to support the Business Combination (including restrictions on the sale, disposition or transfer of the shares of NewAmsterdam Pharma held by him, her or it).

Sponsor Support Agreement

In connection with the execution of the Business Combination Agreement, the FLAC Initial Shareholders, FLAC, the Company and NewAmsterdam Pharma entered into the Support Agreement, pursuant to which the FLAC Initial Shareholders have agreed to

vote (i) in favor of the Business Combination Agreement and the related transactions, including in favor of each Transaction Proposal (as defined in the Business Combination Agreement), (ii) in favor of any other matter reasonably necessary or required to cause the consummation of the Business Combination and related transactions, and (iii) against any proposal that conflicts or materially impedes or interferes with, or would adversely affect or delay the consummation of the Business Combination and related transactions; (b) waive any adjustment to the conversion ratio set forth in FLAC's amended and restated memorandum and articles of association or any other anti-dilution or similar protection with respect to the FLAC Class B Ordinary Shares held by them; and (c) waive any redemption rights, including with respect to FLAC Class A Ordinary Shares purchased in the FLAC IPO or in the aftermarket, in connection with the Business Combination.

Investor Rights Agreement

In connection with the closing of the Business Combination, we entered into the Investor Rights Agreement with the FLAC Initial Shareholders, and certain NewAmsterdam Pharma shareholders, which is filed hereto as Exhibit 10.5, providing for, among other things, subject to the terms thereof, customary registration rights, including demand and piggy-back rights subject to cut-back provisions. We agreed to file a registration statement to register the Ordinary Shares covered by the Investor Rights Agreement no later than 30 days following consummation of the Business Combination.

Pursuant to the Investor Rights Agreement, 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 receive in connection with the Business Combination for six months from the date the Domestication became effective (the "Final Closing Date") of the Business Combination, 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 of the Business Combination. Notwithstanding the foregoing, the restrictions above will end prior to the indicated time periods with respect to 50% of the Ordinary Shares the NewAmsterdam Pharma shareholders and the FLAC Initial Shareholders, as the case may be, receives in connection with the Business Combination, on the earlier of the date that (i) the closing price of an Ordinary Share equals or exceeds \$12.00 per share (subject to certain adjustments) for any 20 trading days within any 30-day trading period commencing at least 150 days after the Final Closing Date of the Business Combination, or (ii) we complete a liquidation, merger, share exchange, reorganization or other similar transaction that results in all of our shareholders having the right to exchange their Ordinary Shares for cash, securities or other property, subject to certain limited exceptions. The restrictions on the remaining 50% of the Ordinary Shares each of the NewAmsterdam Pharma shareholders and the FLAC Initial Shareholders, as the case may be, received in connection with the Business Combination will end prior to the periods indicated above on the date that we complete a liquidation, merger, share exchange, reorganization or other similar transaction that results in all of our shareholders having the right to exchange their Ordinary Shares for cash, securities or other property, subject to certain limited exceptions. The share transfer restrictions above will not apply with respect to sales to cover withholding taxes due upon vesting of equity awards and, in the case of our directors or officers, with respect to the sale of up to 10% of the Ordinary Shares held by each of them. An aggregate of 44,914,642 Ordinary Shares held by former NewAmsterdam Pharma shareholders (including Amgen and MTPC) will have registration rights pursuant to the terms of the Investor Rights Agreement.

Lock-Up Agreements

At the closing of the Business Combination, certain NewAmsterdam Pharma shareholders who are not party to the Investor Rights Agreement (after giving effect to the Merger and the PIPE Financing) including certain of our executive officers, entered into lock-up agreements in the form filed hereto as Exhibit 10.6 (each, a "Lock-Up Agreement"), pursuant to which, among other things, they 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 Final Closing Date of the Business Combination. Notwithstanding the foregoing, the restrictions above will end on the earlier of the date that (i) the closing price of an Ordinary Share equals or exceeds \$12.00 per share (subject to certain adjustments) for any 20 trading days within any 30-day trading period commencing at least 150 after the Final Closing Date of the Business Combination, or (ii) we complete a liquidation, merger, share exchange, reorganization or other similar transaction that results in all of our shareholders having the right to exchange their Ordinary Shares for cash, securities or other property, subject to certain limited exceptions. The share transfer restrictions above will not apply with respect to sales to cover withholding taxes due upon vesting of equity awards and, in the case of our directors or officers, with respect to the sale of up to 10% of the Ordinary Shares held by each of them. Approximately 268,472 Ordinary Shares, or less than 1% of the Ordinary Shares outstanding following the closing of the

Business Combination, are subject to a Lock-Up Agreement. The terms of a Lock-Up Agreement will also apply Ordinary Shares underlying options held by the parties to a Lock-Up Agreement.

NewAmsterdam Pharma Shareholders' Agreement

On January 11, 2021, all of the then existing shareholders of NewAmsterdam Pharma entered into the Fully Amended and Restated Shareholders' Agreement (as amended or supplemented from time to time, the "Shareholder Agreement"). The Shareholder Agreement contained provisions related to the governance of NewAmsterdam Pharma, including memorializing the right of certain investors in NewAmsterdam Pharma to appoint and dismiss members of the board of directors of NewAmsterdam Pharma. Two positions on the board of directors of NewAmsterdam Pharma were reserved for the chief executive officer and chief scientific officer, initially Drs. Michael Davidson and John Kastelein. Jason Dinges, Gaurav Gupta, Sander Slootweg and Juliette Audet were initially appointed by NewAmsterdam Pharma's investors as non-executive directors on the board of directors of NewAmsterdam Pharma.

The Shareholder Agreement also contained transfer restrictions, preemptive rights, co-sale rights, drag along rights and registration rights, among other matters. The Shareholder Agreement was terminated immediately after giving effect to the Exchange.

Chief Executive Officer Loan Agreement

On June 28, 2021, NewAmsterdam Pharma entered into a loan agreement with Dr. Davidson (the "Davidson Loan Agreement") pursuant to which NewAmsterdam Pharma loaned Dr. Davidson €708,571 for the purpose of allowing him to purchase 285,714 depository receipts from Stichting Administratiekantoor EPNAP described below. The loan under the Davidson Loan Agreement bore interest at a per annum rate of 2.75%. The loan was required to be repaid upon the earlier of (i) the tenth anniversary of the effective date of the Davidson Loan Agreement and (ii) an exit, as defined in the Davidson Loan Agreement. Dr. Davidson had the ability to prepay the outstanding principal and accrued interest, in full or in part, with NewAmsterdam Pharma's consent. On July 19, 2022, Dr. Davidson repaid the entire outstanding principal amount and all accrued interest under the Davidson Loan Agreement.

Chief Executive Officer Award Agreement

On June 28, 2021, NewAmsterdam Pharma entered into a founder depository receipt award agreement with Stichting Administratiekantoor EPNAP and Dr. Davidson (the "Davidson Award Agreement") pursuant to which Stichting Administratiekantoor EPNAP issued 285,714 depository receipts for NewAmsterdam Pharma's non-voting convertible shares held by Stichting Administratiekantoor EPNAP (the "Davidson Depository Receipts") at an aggregate subscription price of €708,571 to be paid in accordance with the Davidson Loan Agreement. Dr. Davidson retained ownership of 25% of the Davidson Depository Receipts after twelve months from August 1, 2020 and the remaining 75% vests with 1/36th per month over the following three years. In connection with the Exchange, the shares underlying the Davidson Depository Receipts were exchanged for Ordinary Shares in the same manner as all of NewAmsterdam Pharma's other shares.

Series A Financing

On July 2, 2020, NewAmsterdam Pharma, as borrower, entered into the Convertible Loan Agreement, granting NewAmsterdam Pharma up to €17 million across three tranches of €5.7 million each. NewAmsterdam Pharma drew down on the first tranche on July 2, 2020 and the second tranche on October 12, 2020. On December 30, 2020, NewAmsterdam Pharma entered into the Series A Subscription Agreement to issue Series A Preferred Shares at the Subscription Price for certain investors and the Discounted Subscription Price for the parties to the Convertible Loan Agreement to set off against the Convertible Loan, for up to an aggregate amount of €160 million, set to occur in two tranches. In accordance with the terms of the Convertible Loan Agreement, €11.7 million of outstanding principal amount and unpaid interest was automatically converted into 1,111,155 Series A Preferred Shares at the First Closing. NewAmsterdam Pharma was entitled 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. NewAmsterdam Pharma issued the second tranche of Series A Preferred Shares in February 2022 resulting in gross proceeds to us of €80 million and the issuance of 5,691,430 additional Series A Preferred Shares (the "Milestone Closing").

In February 2022, in connection with the Milestone Closing, NewAmsterdam Pharma's directors, executive officers and holders of more than 10% of its capital stock subscribed for the number of Series A Preferred Shares set out in the table below. The Milestone Closing was contingent on the achievement of certain milestones, namely: at least 50% LDL lowering in the ongoing obicetrapib and ezetimibe Phase 2 combination trial; the hiring of a full-time chief business officer; and confirmation by the FDA that no CVOT would be required for regulatory approval in the United States. After achieving the first two of these milestones, NewAmsterdam

Pharma proceeded with closing the Milestone Closing on February 17, 2022 as permitted by the terms of the Series A Subscription Agreement. Because the Milestone Closing was closed without having achieved all of the milestones, NewAmsterdam Pharma was obligated to pursue a strategic transaction, including a business combination with a special purpose acquisition company.

Investor	Shares of Series A Preferred	Total Subscription Price
Michael Davidson	24,286	€ 340,000
Forbion Capital Fund II Coöperatief U.A.	24,286	€ 340,000
Forbion Capital Fund IV Coöperatief U.A.	1,071,429	€ 15,000,000
Forbion Growth Opportunities Fund I Coöperatief U.A.	714,286	€ 10,000,000
Morningside Venture Investments Limited	1,071,429	€ 15,000,000
Ascendant BioCapital SPV I, LCC—Series 1(1)	357,143	€ 5,000,000

(1) Gaurav Gupta was serving on the board of directors of NewAmsterdam Pharma at the time of the Milestone Closing.

Immediately prior to the Exchange, the Series A Preferred Shares were converted at a 1:1 ratio into shares of NewAmsterdam Pharma ordinary shares and contributed in the Exchange for Ordinary Shares.

PoolCo Shareholders' Agreements

On March 12, 2021, Wester Investments B.V., BioGeneration Ventures II B.V., BioGeneration II Co-Invest II B.V., BGV II Coöperatief U.A., Forbion Capital Fund II Coöperatief U.A., WestCT B.V., LSP Dementia Fund Coöperatieve U.A., Diomedea Medical B.V., LouFré Holding B.V. incorporated NAP PoolCo B.V. ("PoolCo"). The purpose of this entity is holding ordinary shares, non-voting convertible shares, Series A Preferred Shares in the capital of NewAmsterdam Pharma, including any depositary receipts issued for such shares, or options for these depositary receipts (the "Participations").

The shareholders of PoolCo, PoolCo, NewAmsterdam Pharma, Stichting Administratiekantoor NewAmsterdam Pharma and Stichting Administratiekantoor EPNAP (the latter two, the "STAKs") entered into a shareholders agreement (the "PoolCo SHA") to govern, among others, the participation of the shareholders of PoolCo, their indirect participation in NewAmsterdam Pharma, board composition, transfer restrictions, future issuance of Participations and distributions.

In connection with the consummation of the Business Combination, the PoolCo SHA was amended (i) to allow and reflect the Exchange, (ii) to reflect the termination of the Shareholder Agreement, and (iii) to incorporate certain other minor amendments.

Services Agreement

On November 23, 2022, the Company entered into a services agreement with each of its subsidiaries (the "Service Agreement"). The Service Agreement provides that the Company is responsible for providing to each of its direct and indirect subsidiaries certain services in support of their business operations. The Company will provide the services on an ongoing basis and will also include specific tasks such as legal, financial, strategic, monitoring, advisory, IP development, tax and administrative services. The Company provides the services on a cost-plus basis. The Company and each subsidiary may terminate the Service Agreement at any time upon one month's prior notice.

In connection with an internal reorganization NewAmsterdam Pharma entered into various intercompany agreements with its subsidiaries, as described below.

Naarden Lease

On March 1, 2020, NewAmsterdam Pharma and an affiliate of Forbion entered into a services agreement (the "Naarden Lease") pursuant to which the Forbion affiliate leased office space to NewAmsterdam Pharma. NewAmsterdam Pharma pays €3,333 per month in rent. Between March 2020 and September 2020, NewAmsterdam Pharma received a 25% discount on its monthly rent in recognition of the COVID-19 pandemic.

Either party may terminate the Naarden Lease upon one month's prior notice to the other, and with immediate effect in the event the other party is in serious breach and has not cured within a reasonable period of time, but in no event later than 14 days after receiving notice of such breach.

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. 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.

Review, Approval or Ratification of Transactions with Related Persons

We have 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, its 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.

Pre-Business Combination FLAC Related Party Transactions

Registration and Shareholder Rights

The former holders of the Founder Shares, FLAC Private Placement Units, FLAC Private Placement Shares, FLAC Private Placement Warrants, FLAC Class A Ordinary Shares underlying the FLAC Private Placement Warrants and units that may be issued upon conversion of working capital loans, if any, held registration rights pursuant to the registration and shareholder rights agreement entered into upon consummation of the FLAC IPO (the "Registration Rights Agreement"). The holders of these securities were entitled to make up to three demands that FLAC register the Private Placement Warrants, FLAC Class A Ordinary Shares underlying the Private Placement Warrants and FLAC Class B Ordinary Shares. In addition, the holders had certain unlimited "piggy-back" registration rights with respect to certain registration statements filed by FLAC subsequent to its completion of an initial business combination and rights to require FLAC to register for resale such securities pursuant to Rule 415 under the Securities Act provided that the holders propose to sell securities at an aggregate offering price of at least \$10 million. However, the Registration Rights Agreement provided that FLAC will not permit any registration statement filed under the Securities Act to become effective until termination of the applicable lock up period. FLAC will bear the expenses incurred in connection with the filing of any such registration statements.

Further, the holders of the Founder Shares, FLAC Private Placement Units, FLAC Private Placement Shares, FLAC Private Placement Warrants, and FLAC Class A Ordinary Shares underlying the Private Placement Warrants received certain shareholder rights which were to become effective upon the consummation of the Business Combination and continue so long as the Sponsor holds any registrable securities. These rights included, the right of the Sponsor to designate up to six individuals to be nominated to serve as directors of the FLAC Board. FLAC would have been required to use its best efforts to take all necessary and desirable actions so that the Sponsor's nominees remain on the FLAC Board.

At the closing of the Business Combination, the Registration Rights Agreement automatically terminated pursuant to its terms and we entered into the Investor Rights Agreement, pursuant to which the Sponsor is entitled to certain registration rights with respect to the Ordinary Shares. The Investor Rights Agreement provides registration rights to the FLAC Initial Shareholders who hold an aggregate of 4,951,000 Ordinary Shares. The 4,500,000 Ordinary Shares acquired by affiliates of the Sponsor in the PIPE Financing also received registration rights as provided for in the Subscription Agreements. Based on the Sponsor's initial purchase price of \$0.009 for 3,300,000 FLAC Class B ordinary shares and \$10.00 for 501,000 FLAC Class A Ordinary Shares, which were all converted on a 1-for-1 basis in connection with the Business Combination, the Sponsor may experience a potential profit which exceeds that of our other shareholders. As a result, the Sponsor may be willing to sell its Ordinary Shares at a price less than shareholders that acquired our shares in the public market or at higher prices than the price paid by such securityholders. The sale or possibility of sale of these Ordinary Shares, including those pursuant to the Resale Registration Statement, could have the effect of increasing the volatility in the price of the Ordinary Shares or putting significant downward pressure on the price of the Ordinary Shares.

C. INTERESTS OF EXPERTS AND COUNSEL

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. CONSOLIDATED STATEMENTS AND OTHER FINANCIAL INFORMATION

Financial Statements

Please see “*Item 18. Financial Statements*” for a list of the financial statements filed with this Form 20-F.

Legal Proceedings

From time to time we are involved in legal proceedings that arise in the ordinary course of business. We believe that the outcome of these proceedings, if determined adversely, will not have a material adverse effect on our financial position. During the period covered by the audited and approved financial statements contained herein, we have not been a party to or paid any damages in connection with litigation that has had a material adverse effect on our financial position. Any future litigation may result in substantial costs and be a distraction to management and our employees. No assurance can be given that future litigation will not have a material adverse effect on our financial position. See “*Item 3. Key Information—D. Risk factors.*”

Dividends and Dividend Policy

We have never declared or paid any cash dividends and have no plan to declare or pay any dividends on our Ordinary Shares in the foreseeable future. We currently intend to retain any earnings for future operations and expansion.

Our Board of Directors may only pay dividends and other distributions from our reserves to the extent our shareholders’ equity (*eigen vermogen*) exceeds the sum of our paid-in and called-up share capital plus the reserves we must maintain under Dutch law or the Articles of Association and (if it concerns a distribution of profits) after adoption of our statutory annual accounts by 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 our reserves will be at the discretion of the Board of Directors and will depend upon a number of factors, including our 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 our adopted statutory annual accounts will be added to our 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 us. 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*).

B. SIGNIFICANT CHANGES

A discussion of the significant changes in our business can be found under “*Item 4. Information on the Company—A. History and Development of the Company*” and “*Item 4. Information on the Company—B. Business Overview.*”

ITEM 9. THE OFFER AND LISTING

A. OFFER AND LISTING DETAILS

Not applicable.

B. PLAN OF DISTRIBUTION

Not applicable.

C. MARKETS

Our Ordinary Shares are listed on The Nasdaq Global Market under the symbol “NAMS” and our Public Warrants are listed on The Nasdaq Global Market under the symbol “NAMS.W.” Our securities began trading on Nasdaq on November 23, 2023.

D. SELLING SHAREHOLDERS

Not applicable.

E. DILUTION

Not applicable.

F. EXPENSES OF THE ISSUE

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. SHARE CAPITAL

Not applicable.

B. MEMORANDUM AND ARTICLES OF ASSOCIATION

We incorporate by reference into this Annual Report the description of our Articles of Association contained in our registration statement on Form F-1 (Registration No. 333-268888) as filed with the SEC on January 17, 2023.

C. MATERIAL CONTRACTS

We entered into a number of material agreements in connection with the Business Combination. See the section titled “*Item 7. Major Shareholders and Related Party Transactions—B. Related Party Transactions*” for a description of the Business Combination Agreement, the PIPE Financing Subscription Agreements, the Company Support Agreement, the Sponsor Support Agreements, the Investor Rights Agreements and the Lock-Up Agreements.

In June 2022, we entered into the Menarini License. See the section titled “*Item 4. Information on the Company—B. Business Overview—Marketing and Sales*” for a full description of the Menarini License.

Except as otherwise disclosed above and elsewhere in this Annual Report (including the exhibits thereto), we are not currently, and have not been in the last two years, party to any material contract, other than contracts entered into in the ordinary course of business.

D. EXCHANGE CONTROLS

Under Dutch law, there are no exchange controls applicable to the transfer to persons outside of the Netherlands of dividends or other distributions with respect to, or of the proceeds from the sale of, shares of a Dutch company, subject to applicable restrictions under sanctions and measures, including those concerning export control, pursuant to European Union regulations, the Sanctions Act 1977 (*Sanctiewet 1977*) or other legislation, applicable anti-boycott regulations, applicable anti-money-laundering regulations and similar rules and provided that, under certain circumstances, payments of such dividends or other distributions must be reported to the Dutch Central Bank at their request for statistical purposes. There are no special restrictions in the Articles of Association or Dutch law that limit the right of shareholders who are not citizens or residents of the Netherlands to hold or vote shares.

E. TAXATION

United States Federal Income Tax Considerations

The following is a description of the material U.S. federal income tax consequences to the U.S. Holders (as defined below) of owning and disposing of our Ordinary Shares and Warrants, which we refer to collectively as our securities. It is not a comprehensive

description of all tax considerations that may be relevant to a particular person's decision to acquire securities. This discussion applies only to a U.S. Holder that is an initial purchaser of securities pursuant to the offering and that holds our securities as a capital asset for tax purposes (generally, property held for investment). In addition, this discussion does not describe all of the tax consequences that may be relevant in light of a U.S. Holder's particular circumstances, including state and local tax consequences, estate tax consequences, alternative minimum tax consequences, the potential application of the Medicare contribution tax on net investment income, and tax consequences applicable to U.S. Holders subject to special rules, such as:

- banks or insurance companies;
- mutual funds and pension plans;
- U.S. expatriates and certain former citizens or long-term residents of the United States;
- dealers or traders in securities who use a mark-to-market method of tax accounting;
- persons holding Ordinary Shares or Warrants as part of a hedging transaction, "straddle," "hedge," "conversion," "synthetic security," "constructive ownership transaction," "constructive sale" or other integrated transaction for U.S. federal income tax purposes;
- U.S. Holders whose "functional currency" for U.S. federal income tax purposes is not the U.S. dollar;
- brokers, dealers or traders in securities, commodities or currencies;
- tax-exempt organizations, qualified retirement plans, individual retirement accounts or other tax deferred accounts;
- S corporations, partnerships, or other entities or arrangements classified as partnerships for U.S. federal income tax purposes;
- regulated investment companies or real estate investment trusts;
- persons who acquired our Ordinary Shares or Warrants pursuant to the exercise of any employee stock option or otherwise as compensation;
- Corporations that accumulate earnings to avoid U.S. federal income tax;
- persons holding our Ordinary Shares or Warrants in connection with a trade or business or permanent establishment outside the United States; and
- persons who own (directly or through attribution) 10% or more (by vote or value) of our outstanding Ordinary Shares.

If an entity that is classified as a partnership for U.S. federal income tax purposes holds our securities, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. Partnerships holding our securities and partners in such partnerships are encouraged to consult their tax advisors as to the particular U.S. federal income tax consequences of holding and disposing of our securities.

The discussion is based on the Internal Revenue Code of 1986, as amended (the "Code"), administrative pronouncements, judicial decisions, final, temporary and proposed Treasury Regulations, all as of the date hereof, changes to any of which may affect the tax consequences described herein—possibly with retroactive effect.

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

- (A) An individual who is a citizen or individual resident of the United States;
- (B) 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;
- (C) an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- (D) 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.

PERSONS CONSIDERING AN INVESTMENT IN OUR SECURITIES SHOULD CONSULT THEIR OWN TAX ADVISORS AS TO THE PARTICULAR TAX CONSEQUENCES APPLICABLE TO THEM RELATING TO THE

Consequences of Ownership and Disposition of Ordinary Shares or Warrants to U.S. Holders—Application of Passive Foreign Investment Company Rules to U.S. Holders of Ordinary Shares or Warrants

The Company is expected to be treated as a PFIC for the current taxable year, during which the Business Combination was completed, and may be treated as a PFIC for future taxable years. A non-U.S. corporation will be classified as a PFIC for U.S. federal income tax purposes if either (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 its assets in a taxable year (ordinarily determined based on fair market value and averaged quarterly over the year), including its pro rata share of the assets of any corporation in which it is considered to own at least 25% of the shares by value, are held for the production of, or produce, passive income. Passive income generally includes dividends, interest, rents and royalties (other than rents or royalties derived in the active conduct of a trade or business) and gains from the disposition of passive assets. A separate determination must be made after the close of each taxable year as to whether a foreign corporation was a PFIC for that year. Once a foreign corporation is treated as a PFIC it is, with respect to a shareholder during the time it qualifies as a PFIC, and subject to certain exceptions, always treated as a PFIC with respect to such shareholder, regardless of whether it satisfied either of the qualification tests in subsequent years.

There are three separate taxation regimes that could apply to a U.S. Holder of Ordinary Shares or Warrants under the PFIC rules, which are (i) the excess distribution regime (which is the default regime), (ii) the QEF regime, and (iii) the mark-to-market regime (each discussed below). A U.S. Holder who holds (actually or constructively) stock in a foreign corporation during any year in which such corporation qualifies as a PFIC is subject to U.S. federal income taxation under one of these three regimes. The effect of the PFIC rules on a U.S. Holder will depend upon which of these regimes applies to such U.S. Holder. Moreover, dividends paid by a PFIC are not eligible for the lower rates of taxation applicable to qualified dividend income (“QDI”) under any of the foregoing regimes.

Excess Distribution Regime

A U.S. Holder that does not make a QEF election or a mark-to-market election, both as described below, will be subject to the default “excess distribution regime” under the PFIC rules with respect to (i) any gain realized on a sale or other disposition (including a pledge) of Ordinary Shares, and (ii) any “excess distribution” received on the U.S. Holder’s Ordinary Shares (generally, any distributions in excess of 125% of the average of the annual distributions on Ordinary Shares during the preceding three years or the U.S. Holder’s holding period, whichever is shorter).

Generally, under this excess distribution regime: the gain or excess distribution will be allocated ratably over the period during which the U.S. Holder held the Ordinary Shares; the amount allocated to the current taxable year, will be treated as ordinary income; and the amount allocated to prior taxable years will be subject to the highest tax rate in effect for that taxable year and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such year.

The tax liability for amounts allocated to years prior to the year of disposition or excess distribution will be payable generally without regard to offsets from deductions, losses and expenses. In addition, gains (but not losses) a U.S. Holder realizes on the sale of Ordinary Shares cannot be treated as capital gains, even if the U.S. Holder holds the shares as capital assets. Further, no portion of any distribution will be treated as QDI.

QEF Regime

A QEF election is effective for the taxable year for which the election is made and all subsequent taxable years and may not be revoked without the consent of the IRS. If a U.S. Holder makes a timely QEF election with respect to its direct or indirect interest in a PFIC, the U.S. Holder will be required to include in income each year a portion of the ordinary earnings and net capital gains of the PFIC as QEF income inclusions, even if amount is not distributed to the U.S. Holder. Thus, the U.S. Holder may be required to report taxable income as a result of QEF income inclusions without corresponding receipts of cash. U.S. Holders of Ordinary Shares should not expect that they will receive cash distributions from the Company sufficient to cover their respective U.S. tax liability with respect to such QEF income inclusions. In addition, as discussed below, U.S. Holders of Warrants will not be able to make a QEF election with respect to their Warrants.

The timely QEF election also allows the electing U.S. Holder to: (i) generally treat any gain recognized on the disposition of its shares of the PFIC as capital gain; (ii) treat its share of the PFIC's net capital gain, if any, as long-term capital gain instead of ordinary income; and (iii) either avoid interest charges resulting from PFIC status altogether, or make an annual election, subject to certain limitations, to defer payment of current taxes on its share of PFIC's annual realized net capital gain and ordinary earnings subject, however, to an interest charge on the deferred tax computed by using the statutory rate of interest applicable to an extension of time for payment of tax. In addition, net losses (if any) of a PFIC will not pass through to an electing U.S. Holder and may not be carried back or forward in computing such PFIC's ordinary earnings and net capital gain in other taxable years. Consequently, a U.S. Holder may over time be taxed on amounts that as an economic matter exceed our net profits.

A U.S. Holder's tax basis in Ordinary Shares will be increased to reflect QEF income inclusions and will be decreased to reflect distributions of amounts previously included in income as QEF income inclusions. No portion of the QEF income inclusions attributable to ordinary income will be treated as QDI. Amounts included as QEF income inclusions with respect to direct and indirect investments generally will not be taxed again when distributed. U.S. Holders should consult their tax advisors as to the manner in which QEF income inclusions affect their allocable share of the Company's income and their basis in their Ordinary Shares.

The Company intends to determine its PFIC status at the end of each taxable year and intends to satisfy any applicable record keeping and reporting requirements that apply to a QEF, including providing to U.S. Holders, for each taxable year that it determines it is or, in its reasonable determination, may be a PFIC, a PFIC Annual Information Statement containing information necessary for U.S. Holders to make a QEF Election with respect to the Company. The Company will provide such information electronically.

U.S. Holders of Warrants will not be able to make a QEF election with respect to their Warrants. As a result, if a U.S. Holder sells or otherwise disposes of such Warrants (other than upon exercise of such Warrants for cash) and the Company was a PFIC at any time during the U.S. Holder's holding period of such Warrants, any gain recognized generally will be treated as an excess distribution, taxed as described above under "*Excess Distribution Regime*." If a U.S. Holder that exercises such a Warrants properly makes and maintains a QEF election with respect to the newly acquired Ordinary Shares (or has previously made a QEF election with respect to the Ordinary Shares), the QEF election will apply to the newly acquired Ordinary Shares.

Notwithstanding such QEF election, the adverse tax consequences relating to PFIC shares, adjusted to take into account the current income inclusions resulting from the QEF election, will continue to apply with respect to such newly acquired Ordinary Shares (which generally will be deemed to have a holding period for purposes of the PFIC rules that includes the period the U.S. Holder held the Warrants), unless the U.S. Holder makes a purging election under the PFIC rules. Under one type of purging election, the U.S. Holder will be deemed to have sold such shares at their fair market value and any gain recognized on such deemed sale will be treated as an excess distribution, as described above.

Mark-to-Market Regime

Alternatively, a U.S. Holder may make an election to mark marketable shares in a PFIC to market on an annual basis. PFIC shares generally are marketable if: (i) they are "regularly traded" on a national securities exchange that is registered with the Securities Exchange Commission or on the national market system established under Section 11A of the Exchange Act; or (ii) they are "regularly traded" on any exchange or market that the Treasury Department determines to have rules sufficient to ensure that the market price accurately represents the fair market value of the stock.

For these purposes, the securities will be considered regularly traded during any calendar year during which they are traded, other than in de minimis quantities, on at least 15 days during each calendar quarter, on a qualified exchange. Any trades that have as their principal purpose meeting this requirement will be disregarded. Our securities are listed on Nasdaq, which is a qualified exchange for these purposes. Consequently, if our Ordinary Shares remain listed on Nasdaq and are regularly traded, and you are a U.S. Holder of securities, we expect the mark-to-market election would be available to you if we are a classified as a PFIC. Each U.S. Holder should consult its tax advisor as to the whether a mark-to-market election is available or advisable with respect to the securities. U.S. Holders of Warrants will not be able to make a mark-to-market election with respect to their Warrants.

A U.S. Holder that makes a mark-to-market election must include in ordinary income for each year an amount equal to the excess, if any, of the fair market value of the securities at the close of the taxable year over the U.S. Holder's adjusted tax basis in the Ordinary Shares. An electing holder may also claim an ordinary loss deduction for the excess, if any, of the U.S. Holder's adjusted basis in the Ordinary Shares over the fair market value of the shares at the close of the taxable year, but this deduction is allowable only to the extent of any net mark-to-market gains for prior years. Gains from an actual sale or other disposition of the Ordinary Shares will be treated as ordinary income, and any losses incurred on a sale or other disposition of the Ordinary Shares will be treated

as an ordinary loss to the extent of any net mark-to-market gains for prior years. Once made, the election cannot be revoked without the consent of the IRS, unless the securities cease to be marketable.

However, a mark-to-market election generally cannot be made for equity interests in any lower-tier PFICs that we own, unless shares of such lower-tier PFIC are themselves “marketable.” As a result, even if a U.S. Holder validly makes a mark-to-market election with respect to our securities, the U.S. Holder may continue to be subject to the PFIC rules (described above) with respect to its indirect interest in any of our investments that are treated as an equity interest in a PFIC for U.S. federal income tax purposes. U.S. Holders should consult their tax advisors to determine whether any of these elections would be available and if so, what the consequences of the alternative treatments would be in their particular circumstances.

Unless otherwise provided by the IRS, each U.S. shareholder of a PFIC is required to file an annual report on IRS Form 8621. A U.S. Holder’s failure to file the annual report will cause the statute of limitations for such U.S. Holder’s U.S. federal income tax return to remain open with regard to the items required to be included in such report until three years after the U.S. Holder files the annual report, and, unless such failure is due to reasonable cause and not willful neglect, the statute of limitations for the U.S. Holder’s entire U.S. federal income tax return will remain open during such period. U.S. Holders should consult their tax advisors regarding the requirements of filing such information returns under these rules.

WE STRONGLY URGE YOU TO CONSULT YOUR TAX ADVISOR REGARDING THE IMPACT OF OUR PFIC STATUS ON YOUR INVESTMENT IN THE SECURITIES AS WELL AS THE APPLICATION OF THE PFIC RULES TO YOUR INVESTMENT IN THE SECURITIES.

U.S. Federal Income Tax Consequences of Ownership and Disposition of Ordinary Shares or Warrants to U.S. Holders if the Company is not a PFIC

Distributions on Ordinary Shares

The treatment of U.S. Holders of Ordinary Shares or Warrants will be materially different from that described above if the Company is not treated as a PFIC for the taxable year during which the Business Combination was completed. If the Company is not treated as a PFIC for the taxable year during which the Business Combination was completed, the gross amount of any distribution on Ordinary Shares generally will be taxable to a U.S. Holder as ordinary dividend income on the date such distribution is actually or constructively received, to the extent that the distribution is paid out of the Company’s current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Because the Company does not maintain, nor is it required to maintain, calculations of its earnings and profits under U.S. federal income tax principles, it is currently expected that any distributions generally will be reported to U.S. Holders as dividends. Any such dividends generally will not be eligible for the dividends received deduction allowed to corporations in respect of dividends received from other U.S. corporations.

With respect to non-corporate U.S. Holders, dividends will be taxed at the preferential long-term capital gains rate (see “—*Sale, Exchange, Redemption or Other Taxable Disposition of Ordinary Shares or Warrants*” below), provided the applicable holding period is met, if Ordinary Shares are readily tradable on an established securities market in the United States (which they will be if the Ordinary Shares continue to be traded on the Nasdaq) and certain other requirements are met. There can be no assurance that Ordinary Shares will be considered readily tradable on an established securities market in all future years. U.S. Holders should consult their tax advisors regarding the potential availability of the lower rate for any dividends paid with respect to Ordinary Shares.

A U.S. Holder must include any Dutch tax withheld from the dividend payment in the gross amount of the dividend even if the holder does not in fact receive it. The dividend is taxable to the holder when the holder receives the dividend, actually or constructively. The amount of the dividend distribution includible in a U.S. Holder’s income will be the U.S. dollar value of the Euro payments made, determined at the spot Euro/U.S. dollar rate on the date the dividend distribution is includible in income, regardless of whether the payment is in fact converted into U.S. dollars. Generally, any gain or loss resulting from currency exchange fluctuations during the period from the date the dividend payment is included in income to the date the payment is converted into U.S. dollars will be treated as ordinary income or loss and will not be eligible for the special tax rate applicable to qualified dividend income. The gain or loss generally will be income or loss from sources within the United States for foreign tax credit imputation purposes.

Dividends that the Company distributes generally should constitute “passive category income,” or, in the case of certain U.S. Holders, “general category income” for foreign tax credit limitation purposes. The rules relating to the determination of the foreign tax credit limitation are complex, and U.S. Holders should consult their tax advisor to determine whether and to what extent they will be entitled to a credit for Dutch withholding taxes imposed in respect of any dividend the Company distributes.

Sale or Other Taxable Disposition of Ordinary Shares or Warrants

If the Company is not treated as a PFIC for the taxable year during which the Business Combination was completed, a U.S. Holder generally will recognize gain or loss on any sale, exchange, redemption (subject to the discussion below) or other taxable disposition of Ordinary Shares or Warrants in an amount equal to the difference between (i) the amount realized on the disposition and (ii) such U.S. Holder's adjusted tax basis in such securities. Any gain or loss recognized by a U.S. Holder on a taxable disposition of Ordinary Shares or Warrants generally will be capital gain or loss and will be long-term capital gain or loss if the holder's holding period in such shares and/or warrants exceeds one year at the time of the disposition. Preferential tax rates may apply to long-term capital gains of non-corporate U.S. Holders (including individuals). The deductibility of capital losses is subject to limitations.

If the consideration received by a U.S. Holder is in the form of currency other than U.S. dollars, the amount realized will be the U.S. dollar value of the payment received determined by reference to the spot rate of exchange on the date of the sale or other disposition. However, if the securities disposed of in the transaction are treated as traded on an "established securities market" and you are either a cash basis taxpayer or an accrual basis taxpayer that has made a special election (which must be applied consistently from year to year and cannot be changed without the consent of the IRS), you will determine the U.S. dollar value of the amount realized in a non-U.S. dollar currency by translating the amount received at the spot rate of exchange on the settlement date of the sale. If you are an accrual basis taxpayer that is not eligible to or does not elect to determine the amount realized using the spot rate on the settlement date, you will recognize foreign currency gain or loss to the extent of any difference between the U.S. dollar amount realized on the date of sale or disposition and the U.S. dollar value of the currency received at the spot rate on the settlement date.

Exercise or Lapse of a Warrant

Except as discussed below with respect to the cashless exercise of a Warrant, a U.S. Holder generally will not recognize taxable gain or loss upon the exercise of a Warrant for cash. The U.S. Holder's initial tax basis in our Ordinary Shares received upon exercise of the Warrant will generally be an amount equal to the sum of the U.S. Holder's acquisition cost of the Warrant and the exercise price of such Warrant. It is unclear whether a U.S. Holder's holding period for the Ordinary Shares received upon exercise of the Warrant would commence on the date of exercise of the Warrant or the day following the date of exercise of the Warrant; however, in either case the holding period will not include the period during which the U.S. Holder held the Warrants. If a Warrant is allowed to lapse unexercised, a U.S. Holder generally will recognize a capital loss equal to such holder's tax basis in the Warrant.

The tax consequences of a cashless exercise of a Warrant are not clear under current tax law. A cashless exercise may be nontaxable, either because the exercise is not a realization event or because the exercise is treated as a recapitalization for U.S. federal income tax purposes. In either situation, a U.S. Holder's initial tax basis in the Ordinary Shares received generally should equal the holder's adjusted tax basis in the Warrant. If the cashless exercise were treated as not being a realization event, it is unclear whether a U.S. Holder's holding period for the Ordinary Shares would commence on the date of exercise of the Warrant or the day following the date of exercise of the Warrant; in either case, the holding period would not include the period during which the U.S. Holder held the Warrant. If, instead, the cashless exercise were treated as a recapitalization, the holding period of the Ordinary Shares generally would include the holding period of the Warrant.

It is also possible that a cashless exercise of a Warrant will be treated in part as a taxable exchange in which gain or loss is recognized. In such event, a U.S. Holder could be deemed to have surrendered a portion of the Warrants being exercised having a value equal to the exercise price of such Warrants in satisfaction of such exercise price. Although not free from doubt, such U.S. Holder generally should recognize capital gain or loss in an amount equal to the difference between the fair market value of the Warrants deemed surrendered to satisfy the exercise price and the U.S. Holder's adjusted tax basis in such Warrants. In this case, a U.S. Holder's initial tax basis in the Ordinary Shares received would equal the sum of the exercise price and the U.S. holder's adjusted tax basis in the Warrants exercised. It is unclear whether a U.S. Holder's holding period for the Ordinary Shares would commence on the date of exercise of the Warrant or the day following the date of exercise of the Warrant; in either case, the holding period would not include the period during which the U.S. Holder held the Warrant. Due to the uncertainty and absence of authority on the U.S. federal income tax treatment of a cashless exercise, including when a U.S. Holder's holding period would commence with respect to the Ordinary Shares received, U.S. Holders are urged to consult their tax advisors regarding the tax consequences of a cashless exercise.

Information Reporting and Backup Withholding

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer

identification number and certifies that it is not subject to backup withholding on a duly executed IRS Form W-9 or otherwise establishes an exemption.

Backup withholding is not an additional tax. The amount of any backup withholding from a payment to a U.S. Holder may be allowed as a credit against the U.S. Holder's U.S. federal income tax liability and may entitle the U.S. Holder to a refund, provided that the required information is timely furnished to the IRS.

Information with Respect to Foreign Financial Assets

Certain U.S. Holders who are individuals (and, under regulations, certain entities) may be required to report information relating to the securities, subject to certain exceptions (including an exception for securities held in accounts maintained by certain U.S. financial institutions), by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their federal income tax return. A U.S. Holder will not be required to file IRS Form 8938 if the holder timely files IRS Form 8621. Such U.S. Holders who fail to timely furnish the required information may be subject to a penalty. Additionally, if a U.S. Holder does not file the required information, the statute of limitations with respect to tax returns of the U.S. Holder to which the information relates may not close until three years after such information is filed. U.S. Holders should consult their tax advisors regarding their reporting obligations with respect to their ownership and disposition of the securities.

U.S. Treasury Regulations meant to require the reporting of certain tax shelter transactions could be interpreted to cover transactions generally not regarded as tax shelters, including certain foreign currency transactions. Under the applicable U.S. Treasury Regulations, certain transactions are required to be reported to the IRS including, in certain circumstances, a sale, exchange, retirement or other taxable disposition of foreign currency, to the extent that such sale, exchange, retirement or other taxable disposition results in a tax loss in excess of a threshold amount. U.S. Holders should consult their tax advisors to determine the tax return obligations, if any, with respect to our securities, and the receipt of Euro in respect thereof, including any requirement to file IRS Form 8886 (Reportable Transaction Disclosure Statement).

Material Dutch Tax Considerations—Ordinary Shares and Public Warrants

Taxation in the Netherlands

This section only outlines material Dutch tax consequences of the holding and disposal of the Ordinary Shares and the acquisition, holding, exercise and disposal of the Warrants. This section does not purport to describe all possible tax considerations or consequences that may be relevant to a holder or prospective holder of Ordinary Shares or Warrants and does not purport to deal with the tax consequences applicable to all categories of investors, some of which (such as trusts or similar arrangements) may be subject to special rules. In view of its general nature, this section should be treated with corresponding caution.

This section is based on the tax laws of the Netherlands, published regulations thereunder and published authoritative case law, all as in effect on the date hereof, including, for the avoidance of doubt, the tax rates applicable on the date hereof, and all of which are subject to change, possibly with retroactive effect. Any such change may invalidate the contents of this section, which will not be updated to reflect such change. Where this section refers to "the Netherlands" or "Dutch" it refers only to the part of the Kingdom of the Netherlands located in Europe.

This section is intended as general information only and is not Dutch tax advice or a complete description of all Dutch tax consequences relating to the acquisition, holding and disposal of the Ordinary Shares or to the acquisition, holding, exercise and disposal of the Warrants. Holders or prospective holders of Ordinary Shares and Warrants should consult their own tax advisor regarding the Dutch tax consequences relating to the acquisition, holding and disposal of Ordinary Shares and the acquisition, holding, exercise and disposal of Warrants in light of their particular circumstances.

Please note that this section does not describe the Dutch tax consequences for:

- i. a holder of Ordinary Shares or Warrants if such holder has a substantial interest (*aanmerkelijk belang*) or deemed substantial interest (*fictief aanmerkelijk belang*) in us under the Dutch Income Tax Act 2001 (*Wet inkomstenbelasting 2001*). Generally, a holder is considered to hold a substantial interest in us, if such holder alone or, in the case of an individual, together with such holder's partner for Dutch income tax purposes, or any relatives by blood or marriage in the direct line (including foster children), directly or indirectly, holds (i) an interest of 5% or more of the total issued and outstanding capital of the Company or of 5% or more of the issued and outstanding capital of a certain class of shares; or (ii) rights, including Warrants, to acquire, directly or indirectly, such interest; or (iii) certain profit sharing rights that relate to 5% or more of the Company's annual profits or to 5% or more of the Company's liquidation proceeds. A deemed substantial interest may arise

- if a substantial interest (or part thereof) in has been disposed of, or is deemed to have been disposed of, on a non-recognition basis;
- ii. a holder of Ordinary Shares or Warrants if the Ordinary Shares or Warrants held by such holder qualify or qualified as a participation (*deelneming*) for purposes of the Dutch Corporate Income Tax Act 1969 (*Wet op de vennootschapsbelasting 1969*). Generally, a holder's shareholding of, or right to acquire, 5% or more in the Company's nominal paid-up share capital qualifies as a participation. A holder may also have a participation if (a) such holder does not have a shareholding of 5% or more but a related entity (statutorily defined term) has a participation or (b) the Company is a related entity (statutorily defined term);
 - iii. a holder of Ordinary Shares which is or who is entitled to the dividend withholding tax exemption (*inhoudingsvrijstelling*) with respect to any income (*opbrengst*) derived from the Ordinary Shares (as defined in Article 4 of the Dutch Dividend Withholding Tax Act 1965 (*Wet op de dividendbelasting*)). Generally, a holder of Ordinary Shares may be entitled or required to apply, subject to certain other requirements, the dividend withholding tax exemption if it is an entity and holds an interest of 5% or more in the Company's nominal paid-up share capital;
 - iv. pension funds, investment institutions (*fiscale beleggingsinstellingen*) and tax exempt investment institutions (*vrijgestelde beleggingsinstellingen*) (each as defined in the Dutch Corporate Income Tax Act 1969) and other entities that are, in whole or in part, not subject to or exempt from Dutch corporate income tax, entities that have a function comparable to an investment institution or a tax exempt investment institution, as well as entities that are exempt from corporate income tax in their country of residence, such country of residence being another state of the European Union, Norway, Liechtenstein, Iceland or any other state with which the Netherlands has agreed to exchange information in line with international standards;
 - v. a holder of Ordinary Shares or Warrants if such holder is an individual for whom the Ordinary Shares or Warrants or any benefit derived from the Ordinary Shares or Warrants is a remuneration or deemed to be a remuneration for (employment) activities performed by such holder or certain individuals related to such holder (as defined in the Dutch Income Tax Act 2001); and
 - vi. a holder of Rollover Options.

Dividend withholding tax

Dividends distributed by the Company are generally subject to Dutch dividend withholding tax at a rate of 15%. Generally, the Company is responsible for the withholding of such dividend withholding tax at source; the Dutch dividend withholding tax is for the account of the holder of Ordinary Shares.

The expression "dividends distributed" includes, but is not limited to:

- i. distributions in cash or in kind, deemed and constructive distributions and repayments of paid-in capital not recognized for Dutch dividend withholding tax purposes;
- ii. liquidation proceeds, proceeds from the redemption of Ordinary Shares, or proceeds from the repurchase of Ordinary Shares (other than as temporary portfolio investment; *tijdelijke belegging*) by the Company or one of our subsidiaries or other affiliated entities, in each case to the extent such proceeds exceed the average paid-in capital of those Ordinary Shares as recognized for Dutch dividend withholding tax purposes;
- iii. an amount equal to the nominal value of the Ordinary Shares issued or an increase of the nominal value of the Ordinary Shares, to the extent that no related contribution, recognized for Dutch dividend withholding tax purposes, has been made or will be made; and
- iv. partial repayment of the paid-in capital recognized for Dutch dividend withholding tax purposes, if and to the extent that the Company has "net profits" (*zuivere winst*), unless:
 - our general meeting of shareholders has resolved in advance to make such repayment; and
 - the nominal value of the Ordinary Shares concerned has been reduced by an equal amount by way of an amendment to our articles of association. The term "net profits" includes anticipated profits that have yet to be realized.

Corporate legal entities that are resident or deemed to be resident of the Netherlands for Dutch corporate income tax purposes ("Dutch Resident Entities") generally are entitled to an exemption from, or a credit for, any Dutch dividend withholding tax against their Dutch corporate income tax liability. The credit in any given year is, however, limited to the amount of Dutch corporate income

tax payable in respect of the relevant year with an indefinite carry forward of any excess amount. Individuals who are resident or deemed to be resident of the Netherlands for Dutch personal income tax purposes (“Dutch Resident Individuals”) generally are entitled to a credit for any Dutch dividend withholding tax against their Dutch personal income tax liability and to a refund of any residual Dutch dividend withholding tax. The above generally also applies to holders of Ordinary Shares that are neither resident nor deemed to be resident of the Netherlands (“Non-Resident Holders”) if the Ordinary Shares are attributable to a Dutch permanent establishment of such Non-Resident Holder.

A holder of Ordinary Shares resident of a country other than the Netherlands may, depending on such holder’s specific circumstances, be entitled to exemptions from, reduction of, or full or partial refund of, Dutch dividend withholding tax under Dutch domestic tax law, EU law, or treaties for the avoidance of double taxation in effect between the Netherlands and such other country.

Warrants

The exercise of Warrants does in the view of the Company not give rise to Dutch dividend withholding tax, except to the extent (i) the exercise price is below the nominal value of an Ordinary Share (currently, the nominal value per Ordinary Share is € 0.12 and the exercise price is \$ 11.50 and (ii) such difference is not charged against the Company’s share premium reserve recognized for Dutch dividend withholding tax purposes. If any Dutch dividend withholding tax due is not effectively withheld for the account of the relevant holder of a Warrant, Dutch dividend withholding tax shall be due by the Company on a grossed-up basis, meaning that the Dutch dividend withholding tax basis shall be equal to the amount referred to in the preceding sentence multiplied by 100/85. In addition, it cannot be excluded that payments made in consideration for a repurchase or redemption of a Warrant or a full or partial cash settlement of the Warrant are in part subject to Dutch dividend withholding tax. To date, no authoritative case law of the Dutch courts has been made publicly available in this respect.

Exceptions and relief from Dutch dividend withholding tax may apply as set forth in the preceding paragraph.

Dividend stripping

According to Dutch domestic anti-dividend stripping rules, no credit against Dutch tax, exemption from, reduction, or refund of Dutch dividend withholding tax will be granted if the recipient of the dividends the Company paid is not considered the beneficial owner (*uiteindelijk gerechtigde*; as described in the Dutch Dividend Withholding Tax Act 1965) of those dividends. This legislation generally targets situations in which a shareholder retains its economic interest in shares but reduces the withholding tax costs on dividends by a transaction with another party. It is not required for these rules to apply that the recipient of the dividends is aware that a dividend stripping transaction took place. The Dutch State Secretary of Finance takes the position that the definition of beneficial ownership introduced by this legislation will also be applied in the context of a double taxation convention.

Conditional withholding tax on dividends (as of January 1, 2024)

As of January 1, 2024, a Dutch conditional withholding tax will be imposed on dividends distributed by the Company to entities related (*gelieerd*) to us (within the meaning of the Dutch Withholding Tax Act 2021; *Wet bronbelasting 2021*), if such related entity:

- i. is considered to be resident (*gevestigd*) in a jurisdiction that is listed in the yearly updated Dutch Regulation on low-taxing states and non-cooperative jurisdictions for tax purposes (*Regeling laagbelastende staten en niet-coöperatieve rechtsgebieden voor belastingdoeleinden*) (a “Listed Jurisdiction”); or
- ii. has a permanent establishment located in a Listed Jurisdiction to which the Ordinary Shares are attributable; or
- iii. holds the Ordinary Shares with the main purpose or one of the main purposes of avoiding taxation for another person or entity and there is an artificial arrangement or transaction or a series of artificial arrangements or transactions; or
- iv. is not considered to be the beneficial owner of the Ordinary Shares in its jurisdiction of residence because such jurisdiction treats another entity as the beneficial owner of the Ordinary Shares (a hybrid mismatch); or
- v. is not resident in any jurisdiction (also a hybrid mismatch); or
- vi. is a reverse hybrid (within the meaning of Article 2(12) of the Dutch Corporate Income Tax Act 1969), if and to the extent (x) there is a participant in the reverse hybrid which is related (*gelieerd*) to the reverse hybrid, (y) the jurisdiction of residence of such participant treats the reverse hybrid as transparent for tax purposes and (z) such participant would have been subject to the Dutch conditional withholding tax in respect of dividends distributed by the Company without the interposition of the reverse hybrid, all within the meaning of the Dutch Withholding Tax Act 2021.

The Dutch conditional withholding tax on dividends will be imposed at the highest Dutch corporate income tax rate in effect at the time of the distribution (2023: 25.8%). The Dutch conditional withholding tax on dividends will be reduced, but not below zero, by any regular Dutch dividend withholding tax withheld in respect of the same dividend distribution. As such, based on the currently applicable rates, the overall effective tax rate of withholding the regular Dutch dividend withholding tax (as described above) and the Dutch conditional withholding tax on dividends will not exceed the highest corporate income tax rate in effect at the time of the distribution (2023: 25.8%).

Taxes on income and capital gains

Dutch Resident Entities

Generally, if the holder of Ordinary Shares or Warrants is a Dutch Resident Entity, any income derived or deemed to be derived from the Ordinary Shares and Warrants or any capital gains realized on the disposal or deemed disposal or exercise, as applicable of the Ordinary Shares or Warrants is subject to Dutch corporate income tax at a rate of 19% with respect to taxable profits up to €200,000 and 25.8% with respect to taxable profits in excess of that amount (rates and brackets for 2023).

Dutch Resident Individuals

If the holder of Ordinary Shares or Warrants is a Dutch Resident Individual, any income derived or deemed to be derived from the Ordinary Shares and Warrants or any capital gains realized on the disposal or deemed disposal or exercise, as applicable of the Ordinary Shares or Warrants is subject to Dutch personal income tax at the progressive rates (with a maximum of 49.5% in 2023), if:

- i. the Ordinary Shares or Warrants are attributable to an enterprise from which the holder of Ordinary Shares or Warrants derives a share of the profit, whether as an entrepreneur (*ondernemer*) or as a person who has a co-entitlement to the net worth (*medegerechtigd tot het vermogen*) of such enterprise without being a shareholder (as defined in the Dutch Income Tax Act 2001); or
- ii. the holder of Ordinary Shares or Warrants is considered to perform activities with respect to the Ordinary Shares or Warrants that go beyond ordinary asset management (*normaal, actief vermogensbeheer*) or otherwise derives benefits from the Ordinary Shares or Warrants that are taxable as benefits from miscellaneous activities (*resultaat uit overige werkzaamheden*).

Taxation of savings and investments

If the above-mentioned conditions i. and ii. do not apply to the Dutch Resident Individual, the Ordinary Shares and Warrants will be subject to an annual Dutch income tax under the regime for savings and investments (*inkomen uit sparen en beleggen*). Taxation only occurs insofar the Dutch Resident Individual's net investment assets for the year exceed a statutory threshold (*heffingvrij vermogen*). The net investment assets for the year are the fair market value of the investment assets less the fair market value of the liabilities on January 1 of the relevant calendar year (reference date; *peildatum*). The Ordinary Shares and Warrants are included as investment assets. The taxable benefit for the year (*voordeel uit sparen en beleggen*) is taxed at a flat rate of 32% (rate for 2023). Actual income or capital gains realized in respect of the Ordinary Shares and Warrants are as such not subject to Dutch income tax.

The taxable benefit for the year is calculated as follows:

- (i) The Dutch Resident Individual's assets and liabilities taxed under this regime, including the Ordinary Shares and Warrants, are allocated over the following three categories: (a) bank savings (*banktegoeden*), (b) other investments (*overige bezittingen*), including the Ordinary Shares and Warrants, and (c) liabilities (*schulden*).
- (ii) The return (*rendement*) in respect of these assets and liabilities is calculated as follows (the return is at a minimum nil):
 - a) a deemed return on the fair market value of the actual amount of bank savings and cash on January 1 of the relevant calendar year; plus
 - b) a deemed return on the fair market value of the actual amount of other investments, including the Ordinary Shares and Warrants, on January 1 of the relevant calendar year; minus
 - c) a deemed return on the sum of the fair market value of the actual amount of liabilities on January 1 of the relevant calendar year less the statutory threshold for liabilities (*drempel*).

- (iii) The return percentage (%) (*rendementspercentage*) is calculated as follows:
- a) by dividing the return calculated under (ii) above by the net investment assets for the year of the Dutch Resident Individual (*rendementsgrondslag*); multiplied by
 - b) 100.
- (iv) The taxable base (*grondslag sparen en beleggen*) is calculated as follows:
- a) the net investment assets for the year of the Dutch Resident Individual; minus
 - b) the applicable statutory threshold.
- (v) The taxable benefit for the year is equal to the taxable base calculated under (iv) above multiplied by the return percentage calculated under (iii) above.

For the calendar year 2023, the deemed returns for the different investment categories mentioned under (ii) (a) and (c) above have been temporarily set at 0.36% and 2.57%, respectively. The definitive percentages for the year 2023 will be published in the first months of 2024 and will have retroactive effect to January 1, 2023. The deemed return applicable to the other investments (mentioned under (ii) (b) above), including the Ordinary Shares and Warrants is set at 6.17% for the calendar year 2023. Transactions in the three-month period before and after January 1 of the relevant calendar year implemented to arbitrate between the deemed return percentages applicable to bank savings, other investments and liabilities will for this purpose be ignored if the holder of Ordinary Shares or Warrants cannot sufficiently demonstrate that such transactions are implemented for other than tax reasons.

Non-residents of the Netherlands

A holder of Ordinary Shares or Warrants that is neither a Dutch Resident Entity nor a Dutch Resident Individual will not be subject to Dutch income tax in respect of income derived or deemed to be derived from the Ordinary Shares or Warrants or in respect of capital gains realized on the disposal or deemed disposal or exercise, as applicable of the Ordinary Shares or Warrants, provided that:

- i. such holder does not have an interest in an enterprise or deemed enterprise (as defined in the Dutch Income Tax Act 2001 and the Dutch Corporate Income Tax Act 1969, as applicable) which, in whole or in part, is either effectively managed in the Netherlands or carried on through a permanent establishment, a deemed permanent establishment or a permanent representative in the Netherlands and to which enterprise or part of an enterprise the Ordinary Shares or Warrants are attributable; and
- ii. in the event the holder is an individual, such holder does not carry out any activities in the Netherlands with respect to the Ordinary Shares or Warrants that go beyond ordinary asset management and does not otherwise derive benefits from the Ordinary Shares or Warrants that are taxable as benefits from miscellaneous activities in the Netherlands.

Gift and inheritance taxes

Residents of the Netherlands

Gift or inheritance taxes will arise in the Netherlands with respect to a transfer of Ordinary Shares or Warrants by way of a gift by, or on the death of, a holder of Ordinary Shares or Warrants who is resident or deemed resident of the Netherlands at the time of the gift or such holder's death.

Non-residents of the Netherlands

No gift or inheritance taxes will arise in the Netherlands with respect to a transfer of Ordinary Shares or Warrants by way of a gift by, or on the death of, a holder of Ordinary Shares or Warrants who is neither resident nor deemed to be resident of the Netherlands, unless:

- i. in the case of a gift of an Ordinary Share or Warrant by an individual who at the date of the gift was neither resident nor deemed to be resident of the Netherlands, such individual dies within 180 days after the date of the gift, while being resident or deemed to be resident of the Netherlands; or

- ii. in the case of a gift of an Ordinary Share Warrant is made under a condition precedent, the holder of Ordinary Shares or Warrants, as applicable is resident or is deemed to be resident of the Netherlands at the time the condition is fulfilled; or
- iii. the transfer is otherwise construed as a gift or inheritance made by, or on behalf of, a person who, at the time of the gift or death, is or is deemed to be resident of the Netherlands.

For purposes of Dutch gift and inheritance taxes, amongst others, a person that holds the Dutch nationality will be deemed to be resident of the Netherlands if such person has been a resident of the Netherlands at any time during the ten years preceding the date of the gift or such person's death. Additionally, for purposes of Dutch gift tax, amongst others, a person not holding the Dutch nationality will be deemed to be resident of the Netherlands if such person has been a resident of the Netherlands at any time during the twelve months preceding the date of the gift. Applicable tax treaties may override deemed residency.

Value added tax (VAT)

No Dutch VAT will be payable by a holder of Ordinary Shares or Warrants in respect of any payment in consideration for the holding or disposal or exercise, as applicable of the Ordinary Shares or Warrants.

Real Property Transfer Tax

Under circumstances, the Ordinary Shares could, for the purposes of Dutch real property transfer tax (*overdrachtsbelasting*), be treated as real property (*fictieve onroerende zaken*) located in the Netherlands, in which case this tax could be payable upon acquisition of Ordinary Shares.

The Ordinary Shares will generally not be treated as real property if at the time of, or at any time during the year preceding, the acquisition of the Ordinary Shares:

- i. our assets do not and did not include real property situated in the Netherlands; or
- ii. our assets only include and included real property, situated either in or outside the Netherlands, that we do not and did not hold, and currently do not intend to hold, predominantly as a financial investment.

Real property as referred to under (i) and (ii) above includes legal ownership and more limited legal rights over the property (rights in rem) (*zakelijke rechten*) as well as contractual rights that give us economic exposure to the value of such real property, and certain participations or interests in entities that are treated as real property.

Our assets do not include and have not included real property situated in the Netherlands as described above. Consequently, no Dutch real property transfer tax becomes payable upon an acquisition of Ordinary Shares.

Stamp Duties

No Dutch documentation taxes (commonly referred to as stamp duties) will be payable by a holder of Ordinary Shares or Warrants in respect of any payment in consideration for the holding or disposal or exercise, as applicable of the Ordinary Shares or Warrants.

F. DIVIDENDS AND PAYING AGENTS

Not applicable.

G. STATEMENT BY EXPERTS

Not applicable.

H. DOCUMENTS ON DISPLAY

We are subject to the informational requirements of the Exchange Act. Accordingly, we are required to file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K. The SEC maintains an Internet site at www.sec.gov that contains reports, proxy and information statements and other information that issuers, including us, have filed electronically with the SEC. As a foreign private issuer, we are exempt under the Exchange Act from, among other things, the rules prescribing the furnishing and content of proxy statements, and our executive officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not

required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act.

We also make available on our website, free of charge, our Annual Report and the text of our reports on Form 6-K, including any amendments to these reports, as well as certain other SEC filings, as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. Our website address is www.newamsterdampharma.com. The reference to our website is an inactive textual reference only, and information contained therein or connected thereto is not incorporated into this Annual Report.

I. SUBSIDIARY INFORMATION

Not applicable.

ITEM 11. 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, and had a loan receivable balance in 2021, 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. Our 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

The only variable interest-bearing financial instruments are cash. Changes in interest rates may cause variations in interest income and expense resulting from short-term interest-bearing assets. Management does not expect the short-term interest rates to decrease significantly in the immediate foreseeable future, which limits the interest exposure on our cash and current financial assets. Currently our interest rate exposure is not hedged.

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

	Increase /(decrease) in basis points	Effect on profit before tax (€ in thousands)
For the year ended December 31, 2022		
Euro	100	(1,517)
Euro	(100)	1,517
U.S. Dollar	100	(2,867)
U.S. Dollar	(100)	2,867
For the year ended December 31, 2021		
Euro	100	(380)
Euro	(100)	380
U.S. Dollar	100	(150)
U.S. Dollar	(100)	150

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. As of December 31, 2022, our net exposure to foreign currency risk was €268.2 million, compared to €15.9 million as at December 31, 2021.

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.

We are mainly exposed to the currency of U.S. Dollar, British Pounds and Japanese Yen.

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

The following table demonstrates the sensitivity to a possible change in exchange rates against the Euro with all other variables held constant. Additional sensitivity changes to the indicated currencies are expected to be approximately proportionate. The table shows the effect on our profit or loss before tax (due to changes in the value of monetary assets and liabilities and equity). Our exposure to foreign currency changes for all other currencies is not material. There has been no impact to our statements of comprehensive loss or changes in equity other than impacts on retained earnings.

	Effect on profit / (loss) before tax (€ in thousands)	
	10% depreciation	10% appreciation
For the year ended December 31, 2022		
British Pound Sterling	(55)	67
Japanese Yen	34	(41)
U.S. Dollar	(24,361)	29,775
For the year ended December 31, 2021		
British Pound Sterling	(9)	15
Canadian Dollar	—	1
Japanese Yen	(1)	1
U.S. Dollar	(1,360)	1,843

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 of December 31, 2022, derivative warrant liabilities and derivative earnout liability amount to €3.9 million and €7.1 million, respectively.

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

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

Credit Risk

Credit risk is the risk that a counterparty will not meet its obligations under a financial instrument or customer contract, leading to a financial loss. 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 provided a loan to our Chief Executive Officer which bore interest and was secured. On July 19, 2022, Dr. Davidson repaid the entire outstanding principal amount and unpaid interest under the Davidson Loan Agreement, representing a total of €709 thousand.

We perform research and development activities and do not yet have any sales. Therefore, we are able to reclaim Value Added Tax (“VAT”), which is recoverable from tax authorities. Management periodically reviews the recoverability of the balance of input value added tax and believes it is fully recoverable.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. DEBT SECURITIES

Not applicable.

B. WARRANTS AND RIGHTS

Not applicable.

C. OTHER SECURITIES

Not applicable.

D. AMERICAN DEPOSITORY SHARES

Not applicable.

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

A. Defaults

None.

B. Arrears and Delinquencies

None.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

None.

ITEM 15. CONTROLS AND PROCEDURES

A. Disclosure Controls and Procedures

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

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

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

In addition, subsequent to the filing of the Original Form 20-F, management identified an additional material weakness relating to certain errors in the calculation of the Company's basic and diluted loss per share presented in the Affected Financial Statements filed as part of the Original Form 20-F, as discussed in greater detail in the Explanatory Note to this Amendment. This material weakness resulted from a lack of sufficient review of our financial statements, including review to determine the accuracy and completeness of our earnings per share calculations, and resulted in a restatement of the Affected Financial Statements.

We have taken steps, and intend to continue taking steps, to develop a remediation plan designed to address these material weaknesses; however, our overall control environment is still immature and may expose us to errors, losses or fraud. See also "*Item 3. Key Information—D. Risk Factors—We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls 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.*"

B. Management's Annual Report on Internal Control over Financial Reporting

This Annual Report does not include a report of management’s assessment regarding internal control over financial reporting due to a transition period established by rules of the SEC for newly public companies. We will be required to provide an annual management report on the effectiveness of our internal control over financial reporting commencing with our second annual report on Form 20-F, which we expect to file in 2024 with respect to the fiscal year ending December 31, 2023.

C. Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report on the Company’s internal control over financial reporting from the Company’s registered public accounting firm due to a transition period established by rules of the SEC for newly public companies and because we are an emerging growth company under the JOBS Act.

D. Changes in Internal Control Over Financial Reporting

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

ITEM 16. [RESERVED]

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Our Audit Committee members include Louis Lange, Juliette Audet and John W. Smither. Louis Lange and John W. Smither each satisfy the “independence” requirements set forth in Rule 10A-3 under the Exchange Act. Each member of our audit committee is financially literate and Louis Lange qualifies as an “audit committee financial expert,” as such term is defined in the rules of the SEC.

ITEM 16B. CODE OF ETHICS

We have adopted a Code of Business Conduct and Ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. Our Code of Business Conduct and Ethics is available on our website. We intend to disclose any amendment to the code, or any waivers of its requirements, in our Annual Report on Form 20-F. For the year ended December 31, 2022, we did not grant any waivers of the Code of Business Conduct and Ethics.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

	For the Years Ended December 31,	
	2022	2021
	<i>(euro in thousands)</i>	
Audit Fees	248	70
Audit-Related Fees	1,677	—
Tax Fees	—	—
All Other Fees	—	—
Total Fees	1,925	70

For the years ended December 31, 2022 and 2021, Deloitte Accountants B.V. was the Company’s auditor.

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.

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 approved by the Audit Committee.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

We are currently relying on an exemption from the audit committee listing standards contained in Exchange Act Rule 10A-3(b)(1)(i). Juliette Audet, one of the members of our audit committee, does not satisfy the independence requirements set out in Exchange Act Rule 10A-3(b)(1)(i) and as a result our audit committee does not currently consist entirely of independent directors. As permitted by Exchange Act Rule 10A-3(b)(1)(iv), we expect to have an audit committee made up entirely of independent directors within one year of October 18, 2022.

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

During the year ended December 31, 2022, no purchases of our equity securities were made by or on behalf of us or any affiliated purchaser.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

Not applicable.

ITEM 16G. CORPORATE GOVERNANCE

Nasdaq rules provide that foreign private issuers may follow home country practice in lieu of the Nasdaq corporate governance standards, subject to certain exceptions and except to the extent that such exemptions would be contrary to U.S. federal securities laws. The home country practices we follow in lieu of Nasdaq rules are described below:

- In accordance with Dutch law and generally accepted business practices, the Articles of Association do not provide quorum requirements generally applicable to general meetings. Our practice varies from the requirement of Nasdaq Listing Rule 5620(c), which requires that an issuer provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting shares.
- Although we must provide shareholders with an agenda and other relevant documents for our General Meetings, Dutch law does not have a regulatory regime for the solicitation of proxies and the solicitation of proxies is not a generally accepted business practice in the Netherlands, thus our practice will vary from the requirement of Nasdaq Listing Rule 5620(b).
- As permitted by the listing requirements of Nasdaq, we have also opted out of the requirements of Nasdaq Listing Rule 5605(b)(2), which requires the independent directors of an issuer have regularly scheduled meetings with just the other independent directors present.
- We will also rely on the exemptions to the SEC and Nasdaq rules with respect to the independence of our audit committee. These rules require that all members of our audit committee must meet the independence standard for audit committee members within one year of October 18, 2022.

In addition, we have opted out of shareholder approval requirements, as included in the Nasdaq Listing Rules, for the issuance of securities in connection with certain events such as the acquisition of shares or assets of another company (if, due to the potential issuance of ordinary shares, the ordinary shares would have upon issuance voting power equal to or in excess of 20% of the voting power outstanding before the issuance of stock), the establishment of or amendments to equity-based compensation plans for employees, a change of control and certain private placements. Our practice varies from the requirements of Nasdaq Rule 5635, which generally requires that an issuer obtain shareholder approval for the issuance of securities in connection with such events.

Nasdaq Diversity Disclosure

Board Diversity Matrix (As of March 1, 2022)

Country of Principal Executive Offices:	Netherlands
Foreign Private Issuer:	Yes
Disclosure Prohibited under Home Country Law:	No
Total Number of Directors:	8

Part I: Gender Identity	Female	Male	Non-Binary	Did Not Disclose Gender
Directors	1	7		
Part II: Demographic Background				
Underrepresented Individual in Home Country Jurisdiction	—		—	—
LGBTQ+	—		—	—
Did Not Disclose Demographic Background	—	—	—	—

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 17. FINANCIAL STATEMENTS

We have elected to provide financial statements pursuant to Item 18.

ITEM 18. FINANCIAL STATEMENTS

Our audited consolidated financial statements are included at the end of this annual report.

ITEM 19. EXHIBITS

Exhibit

Number	Description
1.1	<u>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).</u>
2.1	<u>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).</u>
2.2	<u>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).</u>
2.3	<u>Warrant Certificate of NewAmsterdam Holdco 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).</u>
2.4*	<u>Description of Share Capital and Articles of Association.</u>
4.1	<u>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).</u>
4.2	<u>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).</u>
4.3	<u>Form of Lock-up Agreement (incorporated by reference to Annex H to the Registration Statement on Form F-4 (File No. 333-266510), filed with the SEC on October 13, 2022).</u>
4.4†	<u>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 (File No. 333-266510), filed with the SEC on October 13, 2022).</u>
4.5	<u>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).</u>
4.6+	<u>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).</u>

4.7+	<u>NewAmsterdam Pharma Company N.V. Long-term Incentive Plan (incorporated by reference to Exhibit 10.13 to the Registration Statement on Form F-1 (File No. 333-268888), filed with the SEC on January 17, 2023).</u>
4.8+	<u>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).</u>
4.9+	<u>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).</u>
8.1	<u>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).</u>
12.1*	<u>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.</u>
12.2*	<u>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.</u>
13.1*	<u>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.</u>
13.2*	<u>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.</u>
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (Formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.

+ Indicates management contract or compensatory plan.

† Certain information has been excluded from the exhibit because it both (i) is not material and (ii) would likely cause competitive harm to the Registrant if publicly disclosed.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Company Name

Date: October 28, 2024

By: /s/ Michael Davidson
Name: Michael Davidson, M.D.
Title: Chief Executive Officer

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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 statement of financial position of NewAmsterdam Pharma Company N.V. and subsidiaries (the "Company") as at December 31, 2022 and 2021, the related consolidated statements of profit or loss and comprehensive loss, changes in equity, and cash flows for each of the three years in the period ended December 31, 2022 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 at December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years ended December 31, 2022 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Restatement of the 2022 financial statements

As discussed in Note 2 and Note 21 to the financial statements, the accompanying financial statements have been restated to correct misstatements in basic and diluted loss per share.

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 Public Company Accounting Oversight Board (United States) (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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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.

/s/ Deloitte Accountants B.V.

Rotterdam, The Netherlands

March 31, 2023 (October 28, 2024 as to the effects of the restatement discussed in Note 2 and Note 21)

We have served as the Company's auditor since 2020.

CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND COMPREHENSIVE LOSS

	Note	For the year ended December 31,		
		2022 <i>Restated</i>	2021 <i>Restated</i>	2020 <i>Restated</i>
<i>(In thousands of Euro, except per share amounts)</i>				
Revenue	5	97,500	—	—
Research and development expenses	6	(82,230)	(25,032)	(4,045)
Selling, general and administrative expenses	7	(22,230)	(4,803)	(1,384)
Share listing expense	9	(60,600)	—	—
Total operating expenses		(165,060)	(29,835)	(5,429)
Operating loss		(67,560)	(29,835)	(5,429)
Finance income	14	11	9	-
Finance expense	22	(271)	(216)	(344)
Fair value change – earnout and warrants	17	(976)	—	—
Foreign exchange gains/(losses)	16	(9,256)	1,443	24
Loss before tax		(78,052)	(28,599)	(5,749)
Income tax expense	12	—	—	—
Loss for the year		(78,052)	(28,599)	(5,749)
Other comprehensive loss, net of tax		—	—	—
Total comprehensive loss for the year, net of tax		(78,052)	(28,599)	(5,749)
Net loss per share (in Euro)	21			
Basic and diluted*		€ (1.97)	€ (1.21)	€ (0.62)

(*) *Restated - see Note 2 and Note 21*

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

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

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

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

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	Note	Issued capital	Share premium	Other reserves	Retained earnings	Total equity
<i>(In thousands of Euro)</i>						
Opening balance at January 1, 2020		25	2,475	—	(328)	2,172
Issuance of non-voting shares		25	(25)	—	—	—
Total profit or loss and comprehensive loss for the year		—	—	—	(5,749)	(5,749)
As at December 31, 2020		50	2,450	—	(6,077)	(3,577)
Opening balance at January 1, 2021		50	2,450	—	(6,077)	(3,577)
Conversion of convertible debt	19	11	11,656	—	—	11,667
Series A - Tranche I	19	49	68,951	—	—	69,000
Issuance of non-voting shares	19	3	706	—	—	709
Share-based compensation		—	—	591	—	591
Total profit or loss and comprehensive loss for the year		—	—	—	(28,599)	(28,599)
As at December 31, 2021		113	83,763	591	(34,676)	49,791
Opening balance at January 1, 2022		113	83,763	591	(34,676)	49,791
Equity contribution (Series A - Tranche II)	19	57	79,623	—	—	79,680
Elimination of old shares (NewAmsterdam Pharma shareholders)	19	(170)	(163,386)	—	—	(163,556)
Equity contribution (NewAmsterdam Pharma shareholders)	19	4,351	159,205	—	—	163,556
Equity contribution (FLAC shareholders)	19	1,582	125,084	—	—	126,666
Equity contribution (PIPE Financing)	19	2,815	225,528	—	—	228,343
Equity contribution (Amgen & MTPC shareholders)	19	1,039	82,121	—	—	83,160
Transaction costs on issue of shares	19	—	(2,534)	—	—	(2,534)
Earnout obligation upon Closing (NewAmsterdam Pharma shareholders)	17	—	—	—	(6,633)	(6,633)
Share-based compensation	20	—	—	4,100	—	4,100
Total profit or loss and comprehensive loss for the year		—	—	—	(78,052)	(78,052)
As at December 31, 2022		9,787	589,404	4,691	(119,361)	484,521

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

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Note	For the year ended December 31,		
		2022	2021	2020
<i>(In thousands of Euro)</i>				
Operating activities:				
Loss before tax		(78,052)	(28,599)	(5,749)
<i>Non-cash adjustments to reconcile loss before tax to net cash flows:</i>				
Depreciation and amortization	13,22	72	14	1
Share listing expense	9	60,600	—	—
Finance income	14	(11)	(9)	—
Finance expense	22	9	2	330
Fair value change - derivative earnout and warrants	17	976	—	—
Foreign exchange gains/(losses)	16	9,256	(1,443)	(24)
Share-based compensation	20	3,922	1,049	—
<i>Changes in working capital:</i>				
Changes in prepayments and other receivables		(3,975)	(4,424)	(1,357)
Changes in trade and other payables		(2,063)	8,246	829
Changes in deferred revenue		17,500	—	—
Interest paid		(262)	—	—
Net cash provided by/(used in) operating activities		7,972	(25,164)	(5,970)
Investing activities:				
Purchase of equipment	13	(13)	(20)	(13)
Repayment of loan receivable	14	728	—	—
Net cash provided by/(used in) investing activities		715	(20)	(13)
Financing activities:				
Proceeds from issuing equity securities (Series A)	19	79,680	69,000	—
Proceeds from issuing equity securities (FLAC shareholders)	4	69,753	—	—
Proceeds from issuing equity securities (PIPE Financing)	4	228,343	—	—
Transaction costs on issue of shares	4	(2,534)	—	—
Proceeds from issuance of borrowings		—	—	11,320
Payments of lease liabilities	22	(65)	(10)	—
Net cash provided by financing activities		375,177	68,990	11,320
Net increase in cash		383,864	43,806	5,337
Foreign exchange differences		1,566	1,425	24
Cash at the beginning of the year		53,092	7,861	2,500
Cash at the end of the year	18	438,522	53,092	7,861

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

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

Note 1 — Group Information

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

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

The consolidated financial statements were authorized by the Company’s Board of Directors (the “**Board**”) for issuance on March 31, 2023.

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

Basis of Preparation

These consolidated financial statements have been prepared in accordance with International Financial Reporting Standards and the interpretations of the IFRS Interpretations Committee (“**IFRS IC**”) as issued by the International Accounting Standards Board (“**IFRS**”). The consolidated financial statements have been prepared on a historical cost basis, unless otherwise disclosed.

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

Basis of Consolidation

The consolidated financial statements include the financial statements of the Company and entities controlled by the Company (its subsidiaries). Control is achieved when the Company:

- has power over the investee;
- is exposed, or has rights, to variable returns from its involvement with the investee; and
- has the ability to use its power to affect its returns.

The Company reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control listed above.

The results of the subsidiaries are included in the consolidated statements of profit or loss and comprehensive loss, consolidated statements of financial position, consolidated statements of changes in equity and consolidated statements of cash flows from the effective date of acquisition up to the date when control ceases to exist. When necessary, adjustments are made to the financial statements of subsidiaries to bring their accounting policies into line with those used by the Company.

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

Going Concern

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

approval, and commercialize finished products containing obicetrapib and ezetimibe. See Note 5 for more information regarding the agreement with Menarini.

In November 2022, the Company completed the Business Combination (as defined below) described in Note 4. The Company received proceeds of €69.8 million as a result of the Business Combination and €228.3 million as a result of the concurrent PIPE Financing. The proceeds from the Business Combination and the upfront payment from Menarini, along with the Company's cash, is expected to be sufficient to fund the Company's anticipated level of operations through 2026.

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

Consolidated Statement of Cash Flows

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

Revenue

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

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

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

The Company estimates the transaction price based on the amount of consideration the Company expects to receive for transferring the promised goods or services in the contract. The consideration may include both fixed consideration and variable consideration. At the inception of each arrangement that includes variable consideration, the Company evaluates the amount of the potential payments and the likelihood that the payments will be received. The Company utilizes either the most likely amount method or expected value method to estimate variable consideration to include in the transaction price based on which method better predicts the amount of consideration expected to be received. The amount included in the transaction price is constrained to the amount for which it is highly probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment.

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

resulting amounts allocated to each performance obligation are consistent with the amounts the Company would expect to receive for each performance obligation.

Revenue is recognized when the customer obtains control of the goods and/or services as provided in the license agreement. The control can be transferred over time or at a point in time – which results in the recognition of revenue over time or at a point in time. The Company recognizes revenue over time as the customer simultaneously receive the benefits provided by the Company's performance, satisfied over time.

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

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

Research and Development Expense

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

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

Selling, General and Administrative Expenses

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

Personnel Expenses

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

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

Share Listing Expense

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

Current Prepayments and Other Receivables

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

Expected credit losses

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

Income Taxes

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

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

In evaluating the probability of recognizing income tax assets, management makes estimates related to the expectation of future taxable income, applicable tax opportunities, tax planning strategies, and recent financial performance. In making its assessment, management gives weight to positive and negative evidence that can be objectively verified. The carrying amount of deferred tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profits will be available to allow all or part of the asset to be recovered.

Current tax

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

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

Deferred taxation

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

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

The carrying amount of deferred tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profits will be available to allow all or part of the asset to be recovered.

Deferred tax is calculated at the tax rates that are expected to apply in the period when the liability is settled or the asset is realized based on tax laws and rates that have been enacted or substantively enacted at the reporting date.

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

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

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

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

Property, Plant and Equipment

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

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

Computer equipment — 20% per annum straight line

The estimated useful life, residual values and depreciation method are reviewed at the end of each reporting period, with the effect of any changes in estimate accounted for on a prospective basis.

Loan Receivable

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

Intangible Assets

Intangible assets comprise of acquired in-process research and development (“**IPR&D**”) and was initially recognized at cost, which was the consideration paid upon the asset acquisition of NewAmsterdam Pharma B.V. in 2020. In connection with the asset acquisition, contingent consideration for future profit rights and IPO share right was initially recognized as contingent consideration and had not been included in the carrying amount of the asset at acquisition. Management deemed that the events considered in estimating the contingent consideration were uncertain and could not be reliably estimated. For these reasons, the Company accounted for the contingent consideration under the cost accumulation model and not initially recognize a liability.

In accordance with IFRS 2, the additional contingent consideration paid for the IPR&D asset in exchange for shares in the Company upon the Closing Date (as defined below) is a share-based payment that is to be recognized at its fair value upon the date of the exchange. Payments for acquired in-process research and development projects obtained through in-licensing arrangements are capitalized as intangible assets provided that they are separately identifiable, controlled by the Company and expected to provide future economic benefits. Refer to Note 4 and Note 15 for additional details behind the acquisition and related cost recognized as IPR&D. The acquired IPR&D asset is regarded as having an indefinite useful life while in-progress as there is no foreseeable limit to the period over which the asset is expected to generate future cash flows, and the useful life will be determined once finalized.

Impairment of Intangible Assets

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

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

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

If the recoverable amount of an asset (or cash-generating unit) is estimated to be less than its carrying amount, the carrying amount of the asset (or cash-generating unit) is reduced to its recoverable amount. An impairment loss is recognized immediately in profit or loss.

At the end of each reporting period, the Group determines if there is any indication a previously impaired intangible asset, excluding goodwill, no longer exists, has had a change in the estimates used to determine the asset's recoverable amount since the impairment loss was recognized. If indicators are identified, the Group determines if the recoverable amount is greater than its carrying amount. If the recoverable amount is greater than its carrying amount, impairment is reversed. Where an impairment loss subsequently reverses, the carrying amount of the asset (or cash-generating unit) is increased to the revised estimate of its recoverable amount, but so that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognized for the asset (or cash-generating unit) in prior years. A reversal of an impairment loss is recognized immediately in profit or loss to the extent that it eliminates the impairment loss which has been recognized for the asset in prior years.

Financial Liabilities

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

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

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

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

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

Cash

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

Equity and reserves

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

An equity instrument is any contract that evidences a residual interest in the assets of an entity after deducting all of its liabilities. Equity instruments issued by the Company are recognized at the proceeds received, net of direct issue costs.

Share-based Payments

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

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

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

Determining the fair value of share-based payment transactions requires the most appropriate valuation for the specific program, which depends on the underlying terms and conditions. This estimate also requires the determination of the most appropriate inputs to the valuation model, including the fair value of the share option. Management determines the value of share-based awards at the respective grant date and at the end of each reporting period with the assistance of a third-party valuation specialist using certain assumptions, such as share price volatility, the determination of an appropriate risk-free interest rate and expected dividends. For options granted under the Company's long-term incentive plan, the total amount to be expensed for services received is determined by reference to the grant date fair value of the options granted as determined using the Black-Scholes pricing model. The Black-Scholes model requires management to make assumptions and judgments about the variables used in the calculations, including the expected term (weighted-average period of time that the options granted are expected to be outstanding), the expected volatility of Ordinary Shares, the related risk-free interest rate and the expected dividend. Changes in these estimates can have a material effect on share-based expenses recognized.

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

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

Leases

Right of use asset

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

Lease liability

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

Fair value measurement

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The definition of a change in accounting estimates was deleted. However, the Board retained the concept of changes in accounting estimates in the Standard with the following clarifications:

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

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

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

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

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

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

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

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

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

Published in 2020 and 2022 respectively, clarify that the classification of liabilities as current or noncurrent is based solely on a company's right to defer settlement for at least 12 months at the reporting date. The right needs to exist at the reporting date and must have substance.

Only covenants with which a company must comply on or before the reporting date may affect this right. Covenants to be complied with after the reporting date do not affect the classification of a liability as current or noncurrent at the reporting date. However, disclosure about covenants is now required to help users understand the risk that those liabilities could become repayable within 12 months after the reporting date.

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

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

Restatement

For the years ended December 31, 2022, 2021 and 2020, the number of shares outstanding at the end of each period was erroneously reported as the weighted average number of shares outstanding during each such period. This restatement corrects the error by calculating the weighted average number of ordinary shares outstanding based upon the number of days each share was outstanding during each of the years ended December 31, 2022, 2021 and 2020. Further, the basic and diluted loss per share, which was calculated based upon the previously reported weighted average number of ordinary shares outstanding, has been calculated and restated based upon the correct weighted average number of shares outstanding for each of the three years ended December 31, 2022, 2021 and 2020.

For additional information on loss per share, please see Note 21 – Loss per share.

The restatement for each period is summarized in the tables below:

<i>(In thousands of Euro, except share and per share amounts)</i>	2020 As previously reported⁽¹⁾	Error Correction	2020 As restated
Loss for the year	(5,749)	-	(5,749)
Weighted average number of ordinary shares ⁽²⁾	5,000,000	(676,230)	4,323,770
Basic and diluted loss per share⁽²⁾	(1.15)	(0.18)	(1.33)
Weighted average number of ordinary shares - as recast ⁽³⁾	10,653,636	(1,440,861)	9,212,775
Basic and diluted loss per share - as recast⁽³⁾	(0.54)	(0.08)	(0.62)

<i>(In thousands of Euro, except share and per share amounts)</i>	2021 As previously reported⁽¹⁾	Error Correction	2021 As restated
Loss for the year	(28,599)	-	(28,599)
Weighted average number of ordinary shares ⁽²⁾	11,325,442	(232,355)	11,093,087
Basic and diluted loss per share⁽²⁾	(2.53)	(0.05)	(2.58)
Weighted average number of ordinary shares - as recast ⁽³⁾	24,131,427	(495,086)	23,636,341
Basic and diluted loss per share - as recast⁽³⁾	(1.19)	(0.02)	(1.21)

<i>(In thousands of Euro, except share and per share amounts)</i>	2022 As previously reported⁽¹⁾	Error Correction	2022 As restated
Loss for the year	(78,052)	-	(78,052)
Weighted average number of ordinary shares	81,559,780	(41,931,692)	39,628,088
Basic and diluted loss per share	(0.96)	(1.01)	(1.97)
Weighted average number of ordinary shares - as recast ⁽³⁾	81,559,780	(41,931,692)	39,628,088
Basic and diluted loss per share - as recast⁽³⁾	(0.96)	(1.01)	(1.97)

- (1) Represents the figures as reported in the Company's Original Form 20-F.
- (2) Does not reflect the impact of the exchange ratio adjustment of approximately 2.13 as disclosed in Note 21 – Loss per Share.
- (3) Recast for the exchange ratio of approximately 2.13 as disclosed in Note 21 – Loss per Share.

Note 3 — Use of Judgments and Estimates

In the application of the Company's accounting policies, which are described above, the Company is required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period or in the period of the revision and future periods if the revision affects both current and future periods.

Revenue

Critical Judgment

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

Critical Estimate

The recognition of revenue over time is based on a pattern that best reflects the satisfaction of the related performance obligation, applying the input method. The input method estimates the satisfaction of the performance obligation as the percentage of total costs that are completed each period compared to the total estimated costs. A cost-based input method of revenue recognition requires management to make estimates of costs to complete the Company's performance obligation. In making such estimates, significant judgment is required to evaluate assumptions related to cost estimates. The cumulative effect of revisions to estimated costs to complete the Company's performance obligation will be recorded in the period in which changes are identified and amounts can be

reasonably estimated. A significant change in these assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods.

The Group allocated the initial transaction price of the Menarini License across both performance obligations based upon a relative stand-alone selling price basis by applying an expected cost plus margin approach. As a result, a portion of the initial transaction price has been deferred from recognition until the expected timing of the associated research and development services have been attained. Such costs and timing are dependent upon forecasted research and development costs which generally follow the remaining term of contracted studies. Significant management judgment is driven by critical estimates such as the forecasted cost and timing of clinical studies, as further described below, which are required to determine the level of effort and the expected period to complete the performance obligations under the Menarini License. Significant changes in the forecasted research and development costs, including when such costs are incurred, can have a material effect on the timing and amount of revenue recognized.

Research and Development Expense

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

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

Financial Derivative Liabilities

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

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

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

Note 4 — FLAC Merger and Capital Reorganization

Prior to November 22, 2022, NewAmsterdam Pharma Company N.V. was a shell company with no active trade or business, and all relevant assets and liabilities, as well as income and expenses, were borne by NewAmsterdam Pharma Holding B.V. ("**NewAmsterdam Pharma**"). FLAC was a special purpose acquisition company ("**SPAC**") incorporated on October 7, 2020 as a Cayman Islands exempted company formed for the purpose of effecting a merger, share exchange, asset acquisition, share purchase,

reorganization or a similar business combination. FLAC completed its initial public offering on December 11, 2020 and listed on the Nasdaq.

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

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

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

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

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

- Immediately following the Merger, each outstanding warrant to purchase a Class A ordinary share, par value \$0.0001 per share, of FLAC became a warrant to purchase one Ordinary Share, on the same contractual terms which resulted in the issuance of 167,000 Private Placement Warrants and 4,600,000 Public Warrants (collectively, the “**Warrants**”).
- Each NewAmsterdam Pharma option that was outstanding and unexercised remained outstanding, and to the extent unvested, such option will continue to vest in accordance with its applicable terms, and at the time of the Exchange, such NewAmsterdam Pharma options became options to purchase, and will when exercised be settled in Ordinary Shares.
- In addition to the transactions described above, 8,656,330 Ordinary Shares were issued to Saga Investments Coöperatief U.A. (“**Amgen**”) and Mitsubishi Tanabe Pharma Corporation (“**MTPC**”) pursuant to their profit rights granted upon the acquisition of Dezima Pharma B.V. (See Note 15).
- Following the Merger, upon the achievement of a certain clinical development milestone, the Company will issue to the Participating Shareholders, Amgen, MTPC and holders of options to purchase shares of NewAmsterdam Pharma prior to the closing of the Business Combination, who were directors, officers, employees or consultants of NewAmsterdam Pharma as of the date of the Business Combination Agreement and who are at the time of achievement of such milestone still providing services to the Group (the “**Participating Optionholders**”), 1,886,137 additional Ordinary Shares (the “**Earnout Shares**”), which in the case of the Participating Optionholders will take the form of awards of restricted stock units. As a result, 1,725,358 Earnout Shares are currently allocated to the Participating Shareholder, including Amgen and MTPC which is

discussed in Note 17. Additionally, 160,778 Earnout Shares are currently allocated to Participating Optionholders discussed in Note 17.

- The Company raised an additional €228.3 million in net equity proceeds through a private placement of ordinary shares with existing shareholders of NewAmsterdam Pharma, FLAC and other new investors (the “**PIPE Financing**”). The PIPE Financing was treated as a capital contribution, which resulted in increases of €2.8 million and €225.5 million to share capital and share premium, respectively.

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

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

Note 5 — Revenue

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

	2022	2021	2020
License revenue attributed from license performance obligation	93,500	—	—
License revenue attributed from R&D performance obligation	4,000	—	—
Total revenue	97,500	—	—

On June 23, 2022, NewAmsterdam Pharma entered into a licensing agreement with A. Menarini International Licensing S.A. (“**Menarini**”) (the “**Menarini License**”), pursuant to which it granted Menarini an exclusive, royalty-bearing, sublicensable license under certain of its intellectual property and its regulatory documentation to undertake post approval development activities and commercialize multiple brands of obicetrapib, either as a sole active ingredient product or in a fixed dose combination with ezetimibe (the “**Licensed Products**”), for any use in the majority of European Countries (“**Menarini Territory**”).

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

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

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

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

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

The Company has also identified an additional performance obligation that consists of the research and development activities related to the general development and commercialization costs related to Licensed Products. The Company determined that this performance obligation is satisfied over time as Menarini simultaneously receives and consumes the benefits of the services provided as they are performed. This is based on the fact that Menarini is receiving status of the research periodically which allows it to make informed decisions in its local development activities. The Company further considered that the licenses and the R&D services are not highly interdependent or highly interrelated because the Group is able to fulfill its promise to transfer the licenses regardless of fulfilling its promise to perform the remaining R&D services. The Company also concluded that the licenses are considered distinct as Menarini could benefit from the licenses together with readily available resources other than the Company's research and development services. The Company utilizes a cost-based input method to measure its progress toward completion of its performance obligation and to calculate the corresponding amount of revenue to recognize each period. The Company believes this is the best measure of progress because other measures do not reflect how the Company transfers its performance obligation to Menarini. In applying the cost-based input method of revenue recognition, the Company uses actual clinical study enrollment figures as well as actual costs incurred relative to budgeted costs expected to be incurred attributable to the Menarini Territory for the performance obligation. These costs consist primarily of third-party contract costs relative to the level of patient enrollment in the studies. Revenue will be recognized based on the level of costs incurred relative to the total budgeted costs for the performance obligation.

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

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

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

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

The deferred revenue has been recognized within current and non-current liabilities based on the expected timing of the associated research and development services. In connection with the Menarini License, €13.0 million has been recognized as current liabilities as the Company expects to perform the associated services within twelve months after the reporting period and the remaining €4.5 million has been recognized as non-current liabilities as of December 31, 2022.

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

	2022	2021	2020
Beginning balance on January 1	—	—	—
Addition of deferred revenue under the Menarini License	21,500	—	—
Revenue recognized under the Menarini License during the period	(4,000)	—	—
Ending balance on December 31	17,500	—	—

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

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

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

Lastly, the Group is entitled to receive tiered royalty payments based on annual aggregate net sales of all Licensed Products in the Menarini Territory, subject to specified reductions upon commercialization. The royalty term begins for each Licensed Product on a country-by-country basis upon the first commercial sale of such product in such country and ends on the later of (i) the expiration of the last-to-expire patent that includes a valid claim, (ii) the expiration of regulatory exclusivity in such country for such Licensed Product and (iii) a specified number of years after the first commercial sale of such Licensed Product in such country (the term of the agreement). In accordance with IFRS 15, the Company recognizes revenue from royalty payments at the later of (i) the occurrence of the subsequent sale; or (ii) the performance obligation to which some or all of the sales-based milestone or royalty payments has been allocated has been satisfied. The Company anticipates recognizing these royalty payments if and when subsequent sales are generated from the Licensed Products.

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

Note 6 — Research and Development Expense

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

	2022	2021	2020
Clinical expenses	(56,795)	(10,842)	(1,450)
Non-clinical expenses	(2,802)	(974)	(41)
Personnel expense (see Note 8)	(6,752)	(3,363)	(994)
Manufacturing costs	(14,850)	(8,338)	(1,236)
Regulatory expenses	(901)	(1,452)	(141)
Other R&D costs	(130)	(63)	(183)
Total research and development expenses	(82,230)	(25,032)	(4,045)

Note 7 — Selling, General and Administrative Expenses

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

	2022	2021	2020
Included in selling expenses:			
Commission expense	(2,485)	—	—
Included in general and administrative expenses:			
Personnel expense (see Note 8)	(5,017)	(1,618)	(265)
Travel costs	(430)	(136)	-
Intellectual property	(1,348)	(708)	(498)
Legal costs	(2,176)	(771)	(382)
Licenses	—	(28)	(6)
Finance and administration	(5,209)	(270)	(151)
Transaction costs	(3,021)	—	—
IT	(25)	(20)	(2)
Rent and office services	(165)	(110)	(55)
Marketing and communication	(1,269)	(710)	(11)
Insurance	(289)	(187)	(11)
Depreciation and amortization	(72)	(14)	(1)
Commercial costs	(134)	—	—
Business development	(260)	(135)	-
Board fees	(69)	(31)	-
Miscellaneous	(261)	(65)	(2)
Total selling, general and administrative expenses	(22,230)	(4,803)	(1,384)

Note 8 — Personnel Expense

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

	2022	2021	2020
Wages, salaries and contracted personnel costs	(7,015)	(3,668)	(1,259)
Other employee benefits	(832)	(264)	-
Share based compensation expense	(3,922)	(1,049)	-
Total personnel expenses	(11,769)	(4,981)	(1,259)

Other employee benefit expenses include employee retirement fund contributions. The Company's wholly owned U.S. subsidiary, NewAmsterdam Pharma Corporation, sponsors a defined contribution retirement plan for employees in the United States. During 2022, 2021 and 2020, total Group contributions to the defined contribution plan amounted to €66 thousand, €35 thousand and nil respectively, included as other employee benefit expenses.

For the years ended December 31, 2022, 2021 and 2020, other employee benefits also include employee health insurance and workers compensation insurance costs amounting to €170 thousand, €75 thousand and nil, employment taxes amounting to €191 thousand, €88 thousand and nil and other miscellaneous expenses amounting to nil, €66 thousand and nil, respectively.

Note 9 — Share Listing Expense

As described in Note 4, the Company issued 13,185,138 shares with a fair value of €126.7 million to former FLAC shareholders, comprised of the fair value of Ordinary Shares that were issued to former FLAC shareholders of €9.61 per share (translated at the per share price of \$9.87 at the Closing Date of FLAC shares). In exchange, the Company received the identifiable net assets held by FLAC, which had a fair value of €66.1 million upon the Closing Date. The excess of the fair value of the equity instruments issued over the fair value of the identified net assets contributed, represents a non-cash expense in accordance with IFRS 2. This one-time

expense as a result of the Merger, in the amount of €60.6 million, is recognized as share listing expense presented as part of the financial result within the Consolidated Statement of Profit or Loss and Comprehensive Loss.

Note 10 — Current Prepayments and Other Receivables

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

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

Note 11 — Trade and Other Payables

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

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

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

Note 12 — Income Taxes

Fiscal Unity in the Netherlands

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

Effective Tax Rate

The table below outlines the reconciliation between the maximum statutory tax rate in 2022 in the Netherlands of 15% for the first €395,000 and 25.8% thereafter (In 2021, this rate was 15% for the first €245,000 and 25% thereafter; in 2020, 16.5% for the first €200,000 and 25% thereafter) and the effective income tax rates for the Company, together with the corresponding amounts, for the years ended December 31:

	2022	2021	2020
Loss before tax	(78,052)	(28,599)	(5,749)
Income tax benefit at statutory tax rate	20,095	7,125	1,420
Difference due to the effects of:			
Movement in unrecognized deferred tax assets resulting from carried forward losses	(20,095)	(7,125)	(1,420)
Income tax expense:	—	—	—
Effective tax rate:	0 %	0 %	0 %

Deferred Taxes

Unused tax losses and other credits carried forwards

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

As at December 31, 2022, tax losses can be carried forward indefinitely to offset against future taxable income, with utilization of such losses limited to 50% of taxable income in excess of € 1 million in any respective year. As at December 31, 2022, at December 31, 2021 and at December 31, 2020, the Group had assessed losses amounting to €78.1 million, €28.6 million and €6.1 million, respectively. In addition, the Group assumed carry forward losses from the following tax periods, resulting from the fiscal unity of the Company and NewAmsterdam Pharma B.V. as associated with the acquisition of its assets and liabilities:

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

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

Note 13 — Property, Plant and Equipment

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

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

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

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

Note 14 — Loans Receivable

Movements in loans receivable were as follows:

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

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

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

Note 15 — Intangible Assets

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

The aggregate contingent consideration to be paid to Amgen and MTPC would become payable upon a traditional underwritten public offering or an exit event, as defined in the 2020 SPA. The profit right shall lapse if the IPO share right is exercised. The IPO share right shall lapse if, as a result of one or more exit events, the profit right is exercised and all of the assets related IPR&D are sold,

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

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

Note 16 — Financial Risk Management

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

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

Market Risk

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

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

Interest rate risk

The only variable interest-bearing financial instruments are cash. Changes in interest rates may cause variations in interest income and expense resulting from short-term interest-bearing assets. Management does not expect the short-term interest rates to decrease significantly in the immediate foreseeable future, which limits the interest exposure on our cash and current financial assets. Currently the interest rate exposure is not hedged.

Interest rate sensitivity

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

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

Foreign currency risk

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

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

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

Foreign currency sensitivity

The Group is mainly exposed to the currency of U.S. Dollar, British Pound Sterling and Japanese Yen. The following table demonstrates the sensitivity to a possible change in exchange rates against the Euro with all other variables held constant. Additional sensitivity changes to the indicated currencies are expected to be approximately proportionate. The table shows the effect on the Group's profit or loss before tax (due to changes in the value of monetary assets and liabilities). The Group's exposure to foreign

currency changes for all other currencies is not material. There is no impact to equity other than to accumulated deficit and no impact to other comprehensive income.

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

Other Market Price Risk

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

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

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

Credit Risk

Credit risk is the risk that a counterparty will not meet its obligations under a financial instrument or customer contract, leading to a financial loss. The Group is exposed to credit risk primarily from its treasury activities, including deposits with banks and financial institutions and has limited credit risk exposure from its operating activities. The Group holds available cash in bank accounts with banks which have investment grade credit ratings. Management periodically reviews the creditworthiness of the banks with which it holds assets.

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

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

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

Liquidity Risk

The Company monitors its risk to a shortage of funds using forecasting planning tools. The Group's objective is to maintain a sufficient level of funding in order to continue its research and development activities and capital and financing obligations. The Group manages liquidity risk by maintaining adequate reserves by continuously monitoring forecast and actual cash flows, and by matching the maturity profiles of financial assets and liabilities.

The Company's main sources of liquidity are obtained through licensing arrangements and financing proceeds. The Company believes that it has sufficient liquidity as a result of the upfront fee received from the Menarini License (see Note 5) and the recent equity funding from the Merger with FLAC which had both occurred in the current reporting period (see Note 4), resulting in the cash balance of €438.5 million at December 31, 2022 (see Note 18).

Maturity profile

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

	On demand	Less than 3 months	3 - 12 months	More than 1 year	Total
At December 31, 2021					
Trade and other payables	—	5,715	880	—	6,595
Value added tax payable	—	2,774	—	—	2,774
Share based payment liabilities	458	—	—	—	458
Lease liability	—	13	40	111	164
Total financial liabilities	458	8,502	920	111	9,991
	On demand	Less than 3 months	3 - 12 months	More than 1 year	Total
At December 31, 2022					
Trade and other payables	—	16,448	92	28	16,568
Share based payment liabilities	1,935	—	—	—	1,935
Lease liability	—	15	63	40	118
Derivative warrant liabilities	3,888	—	—	—	3,888
Derivative earnout liability	—	—	—	7,053	7,053
Total financial liabilities	5,823	16,463	155	7,121	29,562

Capital Management

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

Note 17 — Financial Assets and Liabilities Fair Value

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

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

Derivative Warrant Liabilities

Immediately following the Merger mentioned in Note 4, each outstanding warrant to purchase a Class A ordinary share, par value \$0.0001 per share, of FLAC became a warrant to purchase one Ordinary Share, on substantially the same terms as were in effect immediately prior to the Closing Date which resulted in the issuance of 167,000 Private Placement Warrants and 4,600,000 Public Warrants (collectively, the “**Warrants**”) and were considered part of the net assets of FLAC at the time of the Merger. The Company assumed and continues to hold these warrants on the same terms as before (to the extent applicable). No new warrants were issued and no existing Warrants were exercised or redeemed from the Closing Date to December 31, 2022. At December 31, 2022, the Group had 4,600,000 and 167,000 Public Warrants and Private Placement Warrants outstanding, respectively.

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

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

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

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

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

Derivative Earnout Liability

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

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

Fair value measurements

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

The Private Placement Warrants have been measured at fair value using inputs other than quoted prices included in Level 1 that are observable for the liability (Level 2), since the terms of the Private Placement Warrants are considered to be nearly identical to the

Public Warrants, and the Public Warrants have an observable price in the active market. For these reasons, the measurement of the Private Placement Warrants can be indirectly derived from the quoted price of the Public Warrants.

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

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

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

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

Given the assumed zero dividend rate and the fact that no strike price exists that would have led to any volatility measure relative to the Company's share price, the fair value of the Earnout Shares allocated to Participating Shareholders resulting from the Black-Scholes pricing model is driven by the Company's closing share price as a Level 1 input and the probability of milestone completion as a Level 3 input. As management's judgment of the probability of milestone completion remained constant during the period, the change in fair value resulted from the Company's price per share between the valuations performed at the Closing Date and at December 31, 2022. The resulting per share fair value of the Earnout Shares allocated to Participating Shareholders is €4.09 at December 31, 2022, compared to a per share fair value of €3.84 at the Closing Date.

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

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

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

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

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

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

	Lease liability	Derivative earnout liability	Derivative warrant liabilities	Total liabilities from financing activities
At January 1, 2022	164	—	—	164
Principal paid on lease liabilities	(56)	—	—	(56)
Interest paid on lease liabilities	(9)	—	—	(9)
Total changes from financing cash flows	(65)	—	—	(65)
Effect of changes in foreign exchange rates	10	(243)	(137)	(370)
Interest charges	9	—	—	9
Acquired at Closing Date	—	6,633	3,712	10,345
Change in fair value	—	663	313	976
Total liability-related charges	19	7,053	3,888	10,960
At December 31, 2022	118	7,053	3,888	11,059
	Lease liability	Derivative earnout liability	Derivative warrant liabilities	Total liabilities from financing activities
At January 1, 2021	—	—	—	—
Principal paid on lease liabilities	(8)	—	—	(8)
Interest paid on lease liabilities	(2)	—	—	(2)
Total changes from financing cash flows	(10)	—	—	(10)
Interest charges	2	—	—	2
Capital increases	172	—	—	172
Total liability-related charges	174	—	—	174
At December 31, 2021	164	—	—	164

Note 18 — Cash

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

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

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

Note 19 — Share Capital and Share Premium

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

	Shares	Price per share (in €)	Share Capital (in €'000)	Share Premium (in €'000)	Total (in €'000)
At January 1, 2020	2,500,000	0.01	25	2,475	2,500
Issuance of non-voting shares	2,500,000	0.01	25	-25	-
At January 1, 2021	5,000,000	0.01	50	2,450	2,500
January 2021 Conversion of convertible debt ⁽¹⁾	1,111,115	0.01	11	11,656	11,667
January 2021 Equity contributions (Series A - Tranche I) ⁽¹⁾	4,928,613	0.01	49	68,951	69,000
July 2021 Issuance of non-voting shares	285,714	0.01	3	706	709
At December 31, 2021⁽²⁾	11,325,442	0.01	113	83,763	83,876
February 18, 2022 Equity contribution (Series A - Tranche II) ⁽³⁾	5,691,430	0.01	57	79,623	79,680
At November 22, 2022, prior to exchange	17,016,872	0.01	170	163,386	163,556
November 22, 2022 Elimination old shares (NewAmsterdam Pharma shareholders) ⁽⁴⁾	(17,016,872)	0.01	(170)	(163,386)	(163,556)
November 22, 2022 Share capital increase on conversion (NewAmsterdam Pharma shareholders) ⁽⁴⁾	36,258,312	0.12	4,351	159,205	163,556
November 22, 2022 Equity contribution (FLAC shareholders) ⁽⁵⁾	13,185,138	0.12	1,582	125,084	126,666
November 22, 2022 Equity contribution (PIPE financing) ⁽⁶⁾	23,460,000	0.12	2,815	225,528	228,343
November 22, 2022 Equity contribution (Amgen & MTPC shareholders) ⁽⁷⁾	8,656,330	0.12	1,039	82,121	83,160
November 22, 2022 Transaction costs on issue ⁽⁵⁾ of shares	—	—	—	(2,534)	(2,534)
At December 31, 2022⁽⁸⁾	81,559,780	0.12	9,787	589,404	599,191

- (1) On January 7, 2021, NewAmsterdam Pharma closed a funding round to raise up to €160 million in equity financing, set to occur in two tranches. The first tranche of €69 million occurred upon an initial closing on January 7, 2021 for the issue of 4,928,613 Series A preferred shares on the same date. In connection with the funding round of the first tranche, €11.7 million in outstanding principal and unpaid interest of convertible debt was converted on the same date of the first tranche into 1,111,155 Series A preferred shares.
- (2) At December 31, 2021, the share capital of NewAmsterdam Pharma amounted to €113 thousand, divided into 2,500,000 voting ordinary shares, 2,785,714 non-voting ordinary shares and 6,039,728 Series A preferred shares, each with a nominal value of €0.12 per share.
- (3) On February 18, 2022, NewAmsterdam Pharma received the second tranche financing of €79.7 million for the issuance of 5,691,430 Series A preferred shares, leading to increases in the share capital and share premium amounting to €57 thousand and €79.6 million, respectively, as a result of attainment of certain milestone tranche conditions (the “**Milestone Closing**”), namely: at least 50% LDL lowering in the ongoing obicetrapib and ezetimibe Phase 2 combination trial; the hiring of a full-time chief business officer; and confirmation by the FDA that no CVOT would be required for regulatory approval in the United States. After achieving the first two of these milestones, NewAmsterdam Pharma proceeded with the Milestone Closing as permitted by the terms of the Series A Subscription Agreement. Because the Milestone Closing occurred without having achieved all of the milestones, NewAmsterdam Pharma was obligated to pursue certain strategic transactions, including a business combination with a special purpose acquisition company.
- (4) As described in Note 1 and Note 4, the Company was incorporated in June 2022 with a share capital of €0.12. On November 22, 2022, pursuant to the Business Combination Agreement, NewAmsterdam Pharma shareholders exchanged their interest for Ordinary Shares in the share capital of the Company in accordance with an exchange ratio defined in the Business Combination Agreement of approximately 2.13. Consequently, following this internal reorganization, 17,016,872 NewAmsterdam Pharma shares of €0.01 par value were exchanged for 36,258,312 Ordinary Shares, €0.12 par value per share. As such, share capital increased by €4.2 million and the share premium decreased by the same amount.

- (5) On November 22, 2022, each ordinary share of FLAC was canceled and exchanged for one Ordinary Share resulting in the issuance of 13,185,138 Ordinary Shares, thereby increasing share capital and share premium by €1.6 million and €125.1 million, respectively, which includes the impact of equity related to the IFRS 2 listing charge for €60.6 million (See Note 9) and, inclusive of the issuance of new Ordinary Shares from the PIPE Financing, the deduction of the net of the transaction costs on issuance of new Ordinary Shares amounting to €2.5 million.
- (6) In connection with the Merger, the Company issued 23,460,000 Ordinary Shares to existing shareholders of NewAmsterdam Pharma, FLAC and other new investors through a PIPE Financing, at a price of \$10.00 per Ordinary Share for an aggregate of \$234.6 million in proceeds on the Closing Date. The issuance of the 23,460,000 Ordinary Shares increased share capital and share premium by €2.8 million and €225.5 million, respectively.
- (7) As described in Note 4 and Note 15, the Company also issued 4,910,000 Ordinary Shares and 3,746,330 Ordinary Shares to Amgen and MTPC, respectively, each with a nominal value of €0.12 per share, in order to settle all rights of Amgen and MTPC under the 2020 SPA and Profit Right Agreement, respectively. The issuance of an aggregate of 8,656,330 Ordinary Shares increased share capital and share premium by €1.0 million and €82.1 million, respectively.
- (8) Upon completing the Business Combination, the Company had 81,559,780 Ordinary Shares outstanding with a par value of €0.12 per share, resulting in a share capital of €9.8 million. As of December 31, 2022, the total number of Ordinary Shares outstanding was 81,559,780 with a par value of €0.12 per share.

Note 20 — Share-Based Payments

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

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

Long Term Incentive Plans

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

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

Term and Vesting Period

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

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

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

Prior to the modification on November 22, 2022, NewAmsterdam Pharma introduced a long-term incentive plan (the "**Prior LTIP**") for employees, officers, and other service providers in July 2021. Under this equity-settled plan, NewAmsterdam Pharma granted options on Depositary Receipts ("**DRs**") relating to non-voting ordinary shares and options on non-voting ordinary shares. On July 8, 2021, NewAmsterdam Pharma granted 262,857 Pre-Series A options, 887,116 First Tranche Options, and 814,312 Second Tranche Options. Each option had a four-year vesting period with 25% vesting after one year and the remaining 75% vesting in equal installments over the next following three years. All options under the Prior LTIP were issued with the same terms with the exception

of the Second Tranche Options, which were subject to the following two additional vesting conditions: (i) the Milestone Closing (i.e., the closing of the second tranche of the Series A financing round) having occurred, provided that the Milestone Closing occurs prior to June 1, 2022; and (ii) the Participant's employment, management, or advisory agreement having continued uninterrupted through the date of the Milestone Closing. These additional non-market vesting conditions were met in 2022.

Modifications of Options During the Year

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

The changes related to the NewAmsterdam Pharma Options have been treated as a modification because the Business Combination Agreement outlines that the new award replaces a canceled award; and so it is treated as if the original award had been modified. Each replacement option (i.e., Company Option) shall be subject to the same terms and conditions (including applicable vesting, expiration and forfeiture provisions) that applied to the NewAmsterdam Pharma Option immediately prior to the closing of the Business Combination. Since the change was structured to preserve the value of the NewAmsterdam Pharma Options, the total fair value of the replacement options granted to an employee is the same as the fair value of the NewAmsterdam Pharma Option held immediately before the closing of the transaction. Therefore, no incremental fair value has been granted in relation to the replacement of the NewAmsterdam Pharma Options with Company Options, and the grant date fair value of the original NewAmsterdam Pharma Options will therefore continue to be charged over the original vesting period.

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

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

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

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

As at December 31, 2022, 2,837,865 of the outstanding Company Options are exercisable. The Company Options granted on November 22, 2022 have an exercise price of \$10.00 per option and will expire on November 22, 2032. The options outstanding as of December 31, 2022 and 2021 have a weighted average remaining contractual life of 9.4 years and 9.5 years, respectively. There were no options outstanding as of December 31, 2020.

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

Fair Value of Options Granted

The Black-Scholes option pricing formula has been applied for measuring the fair value of the options granted. The assumptions used to determine the fair value of the options represent management's best estimates. These estimates involve inherent uncertainties and the application of management's judgment, specifically as it relates to share value prior to the Merger, volatility and expected life. The

weighted average fair values and the inputs (ranges) used in the measurement of the fair values of these equity-settled options at the date of grant are summarized below:

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

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

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

Share-Based Payment Expenses Recognized for Options Granted

The fair value of the options is expensed over the relevant vesting periods using the graded vesting method, based on management's estimate of the number of options that will eventually vest. For the years ended December 31, 2022, 2021 and 2020, the total share-based payment expense recognized for the equity-settled options amounted to €3.922 million, €1.049 million and nil, respectively.

In addition, during the years ended December 31, 2022, 2021 and 2020, the Company recognized €1.612 million, €43 thousand and nil as expenses for the employer social security contributions expected to be payable related to these options. The corresponding liability as of December 31, 2022 and 2021 amounts to €1.655 million and €43 thousand, respectively.

Restricted Stock Units ("RSUs")

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

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

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

Chief Executive Officer Restricted Share Award

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

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

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

In connection with the award arrangement, if M. Davidson leaves NewAmsterdam Pharma, all unvested Founder DRs will be cancelled automatically, with simultaneous cancellation of the underlying shares, and against payment by the Company to the participant of the lower of the (i) the purchase price paid and (ii) the fair market value. As the Founder DRs were delivered immediately on receipt for consideration paid by M. Davidson but remain subject to ongoing vesting conditions, to reflect the consideration paid and the potential that the Ordinary Shares may be repurchased, the Company has recognized the consideration as a financial liability until the awards have vested, at which time it will be reclassified to equity provided that M. Davidson remains with the Group. This liability is measured at the lower of the price paid for the Founder DRs and their current fair market value of the Ordinary Shares. The liability for unvested Ordinary Shares as of December 31, 2022 and 2021 amounts to €280 thousand and €458 thousand, respectively.

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

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

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

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

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

Note 21 — Loss per Share

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

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

	December 31, 2021	December 31, 2020
	<i>Restated</i>	<i>Restated</i>
Weighted average number of ordinary shares of NewAmsterdam Pharma	11,093,087	4,323,770
Exchange ratio	2.13	2.13
Adjusted number of shares⁽¹⁾	23,636,341	9,212,775

(1) Recasts for the exchange ratio of approximately of 2.13.

The following table sets forth the computation of basic and diluted loss per share:

<i>(In thousands of Euro, except share and per share amounts)</i>	2022	2021	2020
	<i>Restated</i>	<i>Restated</i>	<i>Restated</i>
Loss for the year	(78,052)	(28,599)	(5,749)
Weighted average number of ordinary shares	39,628,088	11,093,087 ⁽¹⁾	4,323,770 ⁽¹⁾
Basic and diluted loss per share	(1.97)	(2.58)⁽¹⁾	(1.33)⁽¹⁾
Weighted average number of ordinary shares - as recast ⁽²⁾	39,628,088	23,636,341	9,212,775
Basic and diluted loss per share - as recast⁽²⁾	(1.97)	(1.21)	(0.62)

(1) Does not reflect the impact of the exchange ratio adjustment of approximately 2.13.

(2) Recast for the exchange ratio of approximately 2.13.

At December 31, 2022, 2021 and 2020, outstanding share-based awards (see Note 20) was excluded from the calculation because their impact would be anti-dilutive. At December 31, 2022, 2021 and 2020, the total number of potential ordinary shares excluded amounted to 11,146,861, 4,185,360 and 1,111,115, respectively.

Note 22 — Lease

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

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

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

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

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

Note 23 — Related Parties

The following table provides the total amount of transactions that have been entered into with related parties for the relevant financial year ended December 31:

	Related party relationship	Type of transaction	Purchases from	Amounts owed to	Amounts owed by
2022					
FCPM III Services B.V. ("Forbion III")	Common control	Rent and office services	40	12	—
2021					
FCPM III Services B.V. ("Forbion III")	Common control	Rent and office services	20	21	—
Mr. M.H. Davidson	Exec. director & shareholder	Receivables	—	—	718
2020					
FCPM III Services B.V. ("Forbion III")	Common control	Rent and office services	28	3	—
Forbion Capital Partners	Common control	Due diligence and travel	3	—	—
Forbion Capital Fund II Coöperatief U.A. ("Forbion II")	Shareholder	Borrowings	—	10,291 *	—
Forbion Capital Fund IV Coöperatief U.A. ("Forbion IV")	Common control	Borrowings	—	679 *	—
Mr. M.H. Davidson	Exec. director & shareholder	Borrowings	—	679 *	—

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

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

Terms and conditions of transactions with related parties

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

Compensation to Directors and Senior Managers of the Company

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

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

	2022	2021	2020
Short-term employee benefits	2,741	1,505	1,303
Share-based payments	3,203	753	—
Total compensation paid to key management personnel	5,944	2,258	1,303

Additionally, certain non-executive directors of the Company who serve as representatives of the Company's shareholders and as such, have of received cash remuneration from the Company during the years ended December 31, 2022, 2021 and 2020 totaling €61 thousand, €26 thousand and nil, respectively, and share-based payment expenses during the period totaling €62 thousand, €13 thousand and nil, respectively. The remaining non-executive directors receive remuneration directly from certain shareholders (Entities affiliated with Forbion, Frazier Lifesciences Sponsor LLC and affiliates, and Entities affiliated with Bain Capital Life Sciences Investors, LLC) that is not recharged to the Company. The amount of this remuneration is not known by the Company.

Note 24 — Segment Reporting

Operating segments are components of the Company that engage in business activities from which it may incur expenses, for which discrete financial information is available and whose operating results are evaluated regularly by the Company's Chief Operating Decision Maker ("CODM") to make decisions about resources to be allocated to the segment and assess its performance. The activities of the Group are considered to be one segment which is reflected in its organizational structure and internal reporting and comprises the research, development and subsequent commercialization of innovative and proprietary compounds that have a potential therapeutic effect in cardiovascular disease. The Company does not distinguish in its internal reporting different segments, neither business nor geographical segments. The Chief Executive Officer is identified as the CODM and reviews the operating results regularly to make decisions about the resources and to assess overall performance of the Company. Prior to 2022, the Board was identified as the CODM. The change in CODM did not impact any identification of segments.

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

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

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

Note 25 — Supplemental Cash Flow Information

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

	2022	2021	2020
Non-cash financing and investing activities			
IPR&D asset recognized resulting from equity issued to Amgen & MTPC shareholders	83,160	—	—
Derivative earnout obligation assumed on closing	6,633	—	—
Conversion of convertible debt to equity	—	11,667	—
Equity issued to FLAC shareholders in excess of proceeds received	56,913	—	—

Note 26 — Events After the Reporting Period

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

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

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

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

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

DESCRIPTION OF OUR SECURITIES

The following description sets forth certain material terms and provisions of ordinary shares and warrants to purchase ordinary shares of NewAmsterdam Pharma Company N.V. (the “Company,” “we,” “us,” and “our”) that are registered under Section 12 of the U.S. Securities Exchange Act of 1934, as amended. This description also includes a description of the material terms of the Articles of Association and of applicable Dutch law. The following description is intended as a summary only and does not constitute legal advice regarding those matters and should not be regarded as such. The description is qualified in its entirety by reference to the complete text of the Articles of Association, which are attached as an English translation of the official Dutch text as Exhibit 3.1 to the Company’s Annual Report on Form 20-F for the year ended December 31, 2022. We urge you to read the full text of the Articles of Association.

General

We were incorporated pursuant to Dutch law on June 10, 2022. Our corporate affairs are governed by the Articles of Association, the board rules of the Board of Directors, our other internal rules and policies and by Dutch law. We are registered with the Dutch Trade Register under number 86649051. Our corporate seat is in Naarden, the Netherlands, and our office address is Gooimeer 2-35 1411 DC Naarden, the Netherlands.

We were incorporated as a Dutch private limited liability company (*besloten vennootschap met beperkte aansprakelijkheid*) and prior to the closing of the Business Combination became a Dutch public limited liability company (*naamloze vennootschap*).

Share Capital

Authorized Share Capital

We have an authorized share capital in the amount of €48,000,000, divided into 400,000,000 Ordinary Shares, each with a nominal value of €0.12.

Under Dutch law, our authorized share capital is the maximum capital that we may issue without amending the Articles of Association. An amendment of the Articles of Association would require a resolution of General Meeting upon proposal by the Board of Directors.

The Articles of Association will provide that, for as long as any Ordinary Shares are admitted to trading on Nasdaq or on any other regulated stock exchange operating in the United States, the laws of the State of New York will apply to the property law aspects of the Ordinary Shares reflected in the register administered by our transfer agent, subject to certain overriding exceptions under Dutch law.

Ordinary Shares

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

Warrants

In connection with the closing of the Business Combination, we entered into the Warrant Assumption Agreement, and pursuant thereto, each of the warrants to purchase one FLAC Class A Ordinary Share at an exercise price of \$11.50 per share, subject to adjustment (the “FLAC Warrants”) were automatically converted into a Warrant, which such Warrant being subject to the same terms and conditions (including exercisability terms) as were applicable to the corresponding FLAC Warrant immediately prior to the closing of the Business Combination.

Each Warrant entitles the registered holder to purchase one Ordinary Share at a price of \$11.50 per share, subject to adjustment as discussed below, at any time commencing 30 days after the consummation of the Business Combination, provided that we have an effective registration statement under the Securities Act covering the Ordinary Shares issuable upon exercise of the warrants and a current prospectus relating to them is available (or we permit holders to exercise their warrants on a cashless basis under the circumstances specified in the Warrant Assumption Agreement) and such shares are registered, qualified or exempt from registration under the securities, or blue sky, laws of the state of residence of the holder. Pursuant to the Warrant Assumption Agreement, a warrant holder may exercise its warrants only for a whole number of Ordinary Shares. This means only a whole warrant may be exercised at a given time by a warrant holder. No fractional warrants will be issued and only whole warrants will trade. The Warrants will expire five years after the day following the closing of the Business Combination, at 5:00 p.m., New York City time, or earlier upon redemption or liquidation.

We agreed that as soon as practicable, but in no event later than 20 business days after the closing of the Business Combination, we will use commercially reasonable efforts to file with the SEC a registration statement covering the Ordinary Shares issuable upon exercise of the Warrants, and we will use commercially reasonable efforts to cause the same to become effective within 60 business days after the closing of the Business Combination, and to maintain the effectiveness of such registration statement and a current prospectus relating to those Ordinary Shares until the Warrants expire or are redeemed, as specified in the Warrant Assumption Agreement; provided that if the Ordinary Shares are at the time of any exercise of a Warrant not listed on a national securities exchange such that they satisfy the definition of a “covered security” under Section 18(b)(1) of the Securities Act, we may, at our option, require holders of the Warrants who exercise their warrants to do so on a “cashless basis” in accordance with Section 3(a)(9) of the Securities Act and, in the event we do so, we will not be required to file or maintain in effect a registration statement. If a registration statement covering the Ordinary Shares issuable upon exercise of the Warrants is not effective by the 60th day after the closing of the Business Combination, warrant holders may, until such time as there is an effective registration statement and during any period when we have failed to maintain an effective registration statement, exercise warrants on a “cashless

basis” in accordance with Section 3(a)(9) of the Securities Act or another exemption, but we will use our best efforts to register or qualify the shares under applicable blue sky laws to the extent an exemption is not available.

Redemptions of Warrants for cash when the price per Ordinary Share equals or exceeds \$18.00. Once the Warrants become exercisable, we may call the Warrants for redemption (except as described herein with respect to the Private Placement Warrants):

- in whole and not in part;
- at a price of \$0.01 per Warrant;
- upon not less than 30 days’ prior written notice of redemption to each warrant holder; and
- if, and only if, 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”).

We will not redeem the Warrants as described above unless a registration statement under the Securities Act covering the issuance of the Ordinary Shares issuable upon exercise of the Warrants is then effective and a current prospectus relating to those shares is available throughout the 30-day redemption period. 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. As a result, we may redeem the warrants as set forth above even if the holders are otherwise unable to exercise the warrants. So long as the Private Placement Warrants are held by the Sponsor or its designated transferee, they may not be redeemed by the Company.

We have established the last of the redemption criterion discussed above to prevent a redemption call unless there is at the time of the call a significant premium to the warrant exercise price. If the foregoing conditions are satisfied and we issue a notice of redemption of the Warrants, each warrant holder will be entitled to exercise his, her or its warrant prior to the scheduled redemption date. However, the price of the Ordinary Shares may fall below the \$18.00 redemption trigger price (as adjusted for share sub-divisions, share capitalizations, reorganizations, recapitalizations and the like) as well as the \$11.50 (for whole Ordinary Shares) warrant exercise price after the redemption notice is issued.

Redemption of Warrants for cash when the price per Ordinary Share equals or exceeds \$10.00. Once the Warrants become exercisable, we may redeem the outstanding Warrants:

- in whole and not in part;
 - at \$0.10 per warrant upon a minimum of 30 days’ prior written notice of redemption; provided that during such 30 day period holders will be able to exercise their Warrants on a cashless basis prior to redemption and receive that number of Ordinary Shares determined by reference to the table below, based on the redemption date and the “fair market value” of the Ordinary Shares except as otherwise described below; provided, further, that if the Warrants are not exercised on a cashless basis or otherwise during such 30 day period, we will redeem such warrants for \$0.10 per share;
-

- if, and only if, the Reference Value equals or exceeds \$10.00 per share (as adjusted for share subdivisions, share dividends, reorganizations, recapitalizations and the like) on the trading day before we send the notice of redemption to the warrant holders; and
- if the Reference Value is less than \$18.00 per share (as adjusted for share subdivisions, share dividends, reorganizations, recapitalizations and the like), the Private Placement Warrants must also be concurrently called for redemption on the same terms as the outstanding Public Warrants, as described above.

The numbers in the table below represent the number of Ordinary Shares that a warrant holder will receive upon a “cashless” exercise in connection with a redemption by us pursuant to this redemption feature, based on the “fair market value” of the Ordinary Shares on the corresponding redemption date (assuming holders elect to exercise their warrants and such warrants are not redeemed for \$0.10 per warrant), determined based on volume-weighted average price of the Ordinary Shares as reported during the 10 trading days immediately following the date on which the notice of redemption is sent to the holders of warrants, and the number of months that the corresponding redemption date precedes the expiration date of the Warrants, each as set forth in the table below. We will provide our warrant holders with the final fair market value no later than one business day after the 10-trading day period described above ends. So long as the Private Placement Warrants are held by the Sponsor or its designated transferee and the reference value equals or exceeds \$18.00 per share, they may not be redeemed by the Company.

The share prices set forth in the column headings of the table below will be adjusted as of any date on which the number of Ordinary Shares issuable upon exercise of a Warrant or the exercise price of the Warrant is adjusted as set forth under the heading “*Anti-dilution Adjustments*” below. If the number of Ordinary Shares issuable upon exercise of a Warrant is adjusted, the adjusted share prices in the column headings will equal the share prices immediately prior to such adjustment, multiplied by a fraction, the numerator of which is the number of shares deliverable upon exercise of a Warrant immediately prior to such adjustment and the denominator of which is the number of shares deliverable upon exercise of a Warrant as so adjusted. In such an event, the number of Ordinary Shares in the table below shall be adjusted in the same manner and at the same time as the number of shares issuable upon exercise of a Warrant.

Redemption Date (period to expiration of warrants)	Fair Market Value of Ordinary Shares								
	<\$10.00	\$11.00	\$12.00	\$13.00	\$14.00	\$15.00	\$16.00	\$17.00	>\$18.00
60 months	0.261	0.281	0.297	0.311	0.324	0.337	0.348	0.358	0.361
57 months	0.257	0.277	0.294	0.310	0.324	0.337	0.348	0.358	0.361
54 months	0.252	0.272	0.291	0.307	0.322	0.335	0.347	0.357	0.361
51 months	0.246	0.268	0.287	0.304	0.320	0.333	0.346	0.357	0.361
48 months	0.241	0.263	0.283	0.301	0.317	0.332	0.344	0.356	0.361
45 months	0.235	0.258	0.279	0.298	0.315	0.330	0.343	0.356	0.361
42 months	0.228	0.252	0.274	0.294	0.312	0.328	0.342	0.355	0.361
39 months	0.221	0.246	0.269	0.290	0.309	0.325	0.340	0.354	0.361
36 months	0.213	0.239	0.263	0.285	0.305	0.323	0.339	0.353	0.361
33 months	0.205	0.232	0.257	0.280	0.301	0.320	0.337	0.352	0.361
30 months	0.196	0.224	0.250	0.274	0.297	0.316	0.335	0.351	0.361
27 months	0.185	0.214	0.242	0.268	0.291	0.313	0.332	0.350	0.361
24 months	0.173	0.204	0.233	0.260	0.285	0.308	0.329	0.348	0.361
21 months	0.161	0.193	0.223	0.252	0.279	0.304	0.326	0.347	0.361
18 months	0.146	0.179	0.211	0.242	0.271	0.298	0.322	0.345	0.361
15 months	0.130	0.164	0.197	0.230	0.262	0.291	0.317	0.342	0.361
12 months	0.111	0.146	0.181	0.216	0.250	0.282	0.312	0.339	0.361
9 months	0.090	0.125	0.162	0.199	0.237	0.272	0.305	0.336	0.361
6 months	0.065	0.099	0.137	0.178	0.219	0.259	0.296	0.331	0.361
3 months	0.034	0.065	0.104	0.150	0.197	0.243	0.286	0.326	0.361
0 months	—	—	0.042	0.115	0.179	0.233	0.281	0.323	0.361

The exact fair market value and redemption date may not be set forth in the table above, in which case, if the fair market value is between two values in the table or the redemption date is between two redemption dates in the table, the number of Ordinary Shares to be issued for each Warrant exercised will be determined by a straight-line interpolation between the number of Ordinary Shares set forth for the higher and lower fair market values and the earlier and later redemption dates, as applicable, based on a 365 or 366-day year, as applicable. For example, if the volume-weighted average price of the Ordinary Shares as reported during the 10 trading days immediately following the date on which the notice of redemption is sent to the holders of the warrants is \$11.00 per share, and at such time there are 57 months until the expiration of the Warrants, holders may choose to, in connection with this redemption feature, exercise their warrants for 0.277 Ordinary Shares for each whole Warrant. For an example where the exact fair market value and redemption date are not as set forth in the table above, if the volume-weighted average price of the Ordinary Shares as reported during the 10 trading days immediately following the date on which the notice of redemption is sent to the holders of the warrants is \$13.50 per share, and at such time there are 38 months until the expiration of the Warrants, holders may choose to, in connection with this redemption feature, exercise their Warrants for 0.298 Ordinary Shares for each whole Warrant. In no event will the Warrants be exercisable in connection with this redemption feature for more than 0.361 Ordinary Shares per Warrant (subject to adjustment).

This redemption feature is structured to allow for all of the outstanding Warrants to be redeemed when the Ordinary Shares are trading at or above \$10.00 per share, which may be at a time when the trading price of Ordinary Shares is below the exercise price of the Warrants. We have established this redemption feature to provide us with the flexibility to redeem the Warrants without the warrants having to reach the \$18.00 per share threshold set forth above under “*Redemptions of Warrants for cash when the price per Ordinary Share equals or exceeds \$18.00.*” Holders choosing to exercise their Warrants in connection with a redemption pursuant to this feature will, in effect, receive a number of Ordinary Shares for their warrants based on an option pricing model with a fixed volatility input as of the date of the prospectus relating to the FLAC IPO. This redemption right provides us with an additional mechanism by which to redeem all of the outstanding Public Warrants, and therefore have certainty as to our capital structure as the Warrants would no longer be outstanding and would have been exercised or redeemed. We will be required to pay the applicable redemption price to warrant holders if we choose to exercise this redemption right and it will allow us to quickly proceed with a redemption of the Warrants if we determine it is in our best interest to do so. As such, we would redeem the Warrants in this manner when we believe it is in our best interest to update our capital structure to remove the Warrants and pay the redemption price to the warrant holders. As stated above, we can redeem the warrants when the Ordinary Shares are trading at a price starting at \$10.00, which is below the exercise price of \$11.50, because it will provide certainty with respect to our capital structure and cash position while providing warrant holders with the opportunity to exercise their warrants on a cashless basis for the applicable number of Ordinary Shares. If we choose to redeem the Warrants when the Ordinary Shares are trading at a price below the exercise price of the Warrants, this could result in the warrant holders receiving fewer Ordinary Shares than they would have received if they had chosen to wait to exercise their warrants for Ordinary Shares if and when such Ordinary Shares were trading at a price higher than the exercise price of \$11.50.

No fractional Ordinary Shares will be issued upon exercise. If, upon exercise, a holder would be entitled to receive a fractional interest in an Ordinary Share, we will round down to the nearest whole number of the number of Ordinary Shares to be issued to the holder. If, at the time of redemption, the Warrants are exercisable for a security other than the Ordinary Shares pursuant to the Warrant Assumption Agreement, the Warrants may be exercised for such security. At such time as the Warrants become exercisable for a security other than the Ordinary Shares, we will use our commercially

reasonable efforts to register under the Securities Act the security issuable upon the exercise of the Warrants.

A holder of a Warrant may notify us in writing in the event it elects to be subject to a requirement that such holder will not have the right to exercise such warrant, to the extent that after giving effect to such exercise, such person (together with such person's affiliates), to the warrant agent's actual knowledge, would beneficially own in excess of 9.8% (as specified by the holder) of the Ordinary Shares issued and outstanding immediately after giving effect to such exercise.

Anti-dilution Adjustments. If the number of outstanding Ordinary Shares is increased by a capitalization or share dividend payable in Ordinary Shares, or by a sub-divisions of Ordinary Shares or other similar event, then, on the effective date of such capitalization or share dividend, sub-divisions or similar event, the number of Ordinary Shares issuable on exercise of each Warrant will be increased in proportion to such increase in the outstanding Ordinary Shares. A rights offering made to all or substantially all holders of Ordinary Shares entitling holders to purchase Ordinary Shares at a price less than the "historical fair market value" (as defined below) will be deemed a share dividend of a number of Ordinary Shares equal to the product of (i) the number of Ordinary Shares actually sold in such rights offering (or issuable under any other equity securities sold in such rights offering that are convertible into or exercisable for Ordinary Shares) and (ii) one minus the quotient of (x) the price per Ordinary Share paid in such rights offering and (y) the historical fair market value. For these purposes, (i) if the rights offering is for securities convertible into or exercisable for Ordinary Shares, in determining the price payable for Ordinary Shares, there will be taken into account any consideration received for such rights, as well as any additional amount payable upon exercise or conversion and (ii) "historical fair market value" means the volume-weighted average price of Ordinary Shares as reported during the 10 trading day period ending on the trading day prior to the first date on which the Ordinary Shares trade on the applicable exchange or in the applicable market, regular way, without the right to receive such rights.

In addition, if we, at any time while the Warrants are outstanding and unexpired, pay a dividend or make a distribution in cash, securities or other assets to all or substantially all the holders of Ordinary Shares on account of such Ordinary Shares (or other securities into which the Warrants are convertible), other than (a) as described above, (b) any cash dividends or cash distributions which, when combined on a per share basis with all other cash dividends and cash distributions paid on the Ordinary Shares during the 365-day period ending on the date of declaration of such dividend or distribution does not exceed \$0.50 (as adjusted to appropriately reflect any other adjustments and excluding cash dividends or cash distributions that resulted in an adjustment to the exercise price or to the number of Ordinary Shares issuable on exercise of each Warrant) but only with respect to the amount of the aggregate cash dividends or cash distributions equal to or less than \$0.50 per share, by the amount of cash and/or the fair market value of any securities or other assets paid on each Ordinary Share in respect of such event.

If the number of outstanding Ordinary Shares is decreased by a consolidation, combination, reverse share sub-division or reclassification of Ordinary Shares or other similar event, then, on the effective date of such consolidation, combination, reverse share sub-division, reclassification or similar event, the number of Ordinary Shares issuable on exercise of each warrant will be decreased in proportion to such decrease in outstanding Ordinary Shares.

Whenever the number of Ordinary Shares purchasable upon the exercise of the Warrants is adjusted, as described above, the Warrant exercise price will be adjusted by multiplying the Warrant exercise price immediately prior to such adjustment by a fraction (x) the numerator of which will be the number of Ordinary Shares purchasable upon the exercise of the Warrants immediately prior to such adjustment and

(y) the denominator of which will be the number of Ordinary Shares so purchasable immediately thereafter.

In case of any reclassification or reorganization of the outstanding Ordinary Shares (other than those described above or that solely affects the par value of such Ordinary Shares), or in the case of any merger or consolidation of the Company with or into another corporation (other than a consolidation or merger in which we are the continuing corporation and that does not result in any reclassification or reorganization of our issued and outstanding Ordinary Shares), or in the case of any sale or conveyance to another corporation or entity of our assets or other property as an entirety or substantially as an entirety in connection with which we are dissolved, the holders of the Warrants will thereafter have the right to purchase and receive, upon the basis and upon the terms and conditions specified in the Warrants and in lieu of the Ordinary Shares immediately theretofore purchasable and receivable upon the exercise of the rights represented thereby, the kind and amount of Ordinary Shares or other securities or property (including cash) receivable upon such reclassification, reorganization, merger or consolidation, or upon a dissolution following any such sale or transfer, that the holder of the Warrants would have received if such holder had exercised their Warrants immediately prior to such event. If less than 70% of the consideration receivable by the holders of Ordinary Shares in such a transaction is payable in the form of Ordinary Shares in the successor entity that is listed for trading on a national securities exchange or is quoted in an established over-the-counter market, or is to be so listed for trading or quoted immediately following such event, and if the registered holder of the Warrant properly exercises the Warrant within thirty days following public disclosure of such transaction, the warrant exercise price will be reduced as specified in the Warrant Assumption Agreement based on the Black-Scholes value (as defined in the Warrant Assumption Agreement) of the Warrant. The purpose of such exercise price reduction is to provide additional value to holders of the warrants when an extraordinary transaction occurs during the exercise period of the Warrants pursuant to which the holders of the Warrants otherwise do not receive the full potential value of the Warrants.

The Warrants have been issued in registered form under a Warrant Assumption Agreement between Continental Stock Transfer & Trust Company, as warrant agent, and us. The Warrant Assumption Agreement provides that the terms of the Warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision or correct any mistake, including to conform the provisions of the Warrant Assumption Agreement to the description of the terms of the Warrants and the Warrant Assumption Agreement set forth in Exhibit 4.1 in this Annual Report, but requires the approval by the holders of at least 65% of the then outstanding Public Warrants to make any change that adversely affects the interests of the registered holders. You should review a copy of the Warrant Assumption Agreement filed as an exhibit hereto, for a complete description of the terms and conditions applicable to the Warrants. The warrant holders do not have the rights or privileges of holders of Ordinary Shares and any voting rights until they exercise their warrants and receive Ordinary Shares. After the issuance of Ordinary Shares upon exercise of the Warrants, each holder will be entitled to one vote for each Ordinary Share held of record on all matters to be voted on by shareholders.

We have agreed that, subject to applicable law, any action, proceeding or claim against us arising out of or relating in any way to the Warrant Assumption Agreement 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 we irrevocably submit to such jurisdiction, which jurisdiction will be the exclusive forum for any such action, proceeding or claim. This provision applies to claims under the Securities Act but does not apply to claims under the Exchange Act or any claim for which the federal district courts of the United States of America are the sole and exclusive forum.

Shareholders' Register

Pursuant to Dutch law and the Articles of Association, we must keep our shareholders' register accurate and current. The Board of Directors keeps the shareholders' register and records names and addresses of all holders of registered shares, showing the date on which the shares were acquired, the date of the acknowledgement by or notification of us as well as the amount paid on each share. The register also includes the names and addresses of those with a right of usufruct (*vruchtgebruik*) on registered shares belonging to another or a pledge (*pandrecht*) in respect of such shares. The Ordinary Shares offered in this offering will be held through DTC. Therefore, DTC or its nominee will be recorded in the shareholders' register as the holder of those Ordinary Shares. The Ordinary Shares will be in registered form (*op naam*). We may issue share certificates (*aandeelbewijzen*) for registered shares in such form as may be approved by the Board of Directors.

Except as otherwise provided or allowed by Dutch law, the issue or transfer of an Ordinary Share shall require a deed to that effect and, in the case of a transfer and unless we are a party to the transaction, acknowledgement of the transfer by us. For as long as any ordinary shares are admitted to trading on Nasdaq or on any other regulated stock exchange operating in the United States of America, the laws of the State of New York shall apply to the property law aspects of the Ordinary Shares (including the statutory provisions concerning the transfer and ownership of legal title to Ordinary Shares) reflected in the register administered by the transfer agent.

Corporate Objectives

Pursuant to the Articles of Association, our main corporate objectives are:

- to develop, conduct research, produce, commercialize, market and sell medicines in general and innovative medicines for cardiovascular diseases in particular;
- to incorporate, to participate in, to finance, to hold any other interest in and to conduct the management or supervision of other entities, companies, partnerships and businesses;
- to provide administrative, technical, financial, economic or other services to other entities, companies, partnerships and businesses;
- to acquire, to manage, to invest, to exploit, to encumber and to dispose of assets and liabilities;
- to furnish guarantees, to provide security, to warrant performance in any other way and to assume liability, whether jointly and severally or otherwise, in respect of obligations of group companies or other parties; and
- to do anything which, in the widest sense, is connected with or may be conducive to the objects described above.

Limitations on the Rights to Own Securities

Ordinary Shares may be issued to individuals, corporations, trusts, estates of deceased individuals, partnerships and unincorporated associations of persons. The Articles of Association contain no limitation on the rights to own Ordinary Shares and no limitation on the rights of non-residents of the Netherlands or foreign shareholders to hold or exercise voting rights.

Limitation on Liability and Indemnification Matters

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.

Federal Forum Provision

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 U.S. Securities Act of 1933, as amended, or the U.S. Securities Exchange Act of 1934, as amended, to the fullest extent permitted by applicable law, will be the U.S. federal district courts.

Shareholders' Meeting

General Meetings must be held in the Netherlands in any of the locations specified in the Articles of Association. The annual General Meeting must be held within six months of the end of each financial year. Additional extraordinary General Meetings may also be held, whenever considered appropriate by the Board of Directors and shall be held within three months after the Board of Directors has considered it to be likely that our shareholders' equity (*eigen vermogen*) has decreased to an amount equal to or lower than half of our paid-in and called up share capital, in order to discuss the measures to be taken if so required.

Pursuant to Dutch law, one or more shareholders or others with meeting rights under Dutch law who jointly represent at least one-tenth of our issued share capital may request that we convene a general meeting, setting out in detail the matters to be discussed. If the Board of Directors has not taken the steps

necessary to ensure that such meeting can be held within six weeks after the request, the proponent(s) may, on their application, be authorized by the competent Dutch court in preliminary relief proceedings to convene a General Meeting. The court shall disallow the application if it does not appear that the proponent(s) has/have previously requested the Board of Directors to convene a General Meeting and the Board of Directors has not taken the necessary steps so that the General Meeting could be held within six weeks after the request. The application shall also be disallowed if the proponent(s) has/have not demonstrated to have a reasonable interest in the convening of the General Meeting.

General Meetings must be convened by an announcement published in a Dutch daily newspaper with national distribution. The notice must state the agenda, the time and place of the meeting, the record date (if any), the procedure for participating in the General Meeting by proxy, as well as other information as required by Dutch law. The notice must be given at least 15 calendar days prior to the day of the meeting. The agenda for the annual general meeting shall include, among other things, the adoption of our statutory annual accounts, appropriation of our profits and proposals relating to the composition of the Board of Directors, including the filling of any vacancies. In addition, the agenda shall include such items as have been included therein by the Board of Directors. The agenda shall also include such items requested by one or more shareholders or others with meeting rights under Dutch law representing at least 3% of our issued share capital. These requests must be made in writing or by electronic means and received by the Board of Directors at least 60 days before the day of the meeting. No resolutions shall be adopted on items other than those that have been included in the agenda.

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 of our 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. 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 explore 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 has been previously invoked or (ii) if a shareholder holds at least 75% of our issued share capital as a consequence of a successful public bid.

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 of our 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 consult with shareholders representing at least 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 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 on our website in respect of its policy and conduct of affairs during the cooling-off period. 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 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 the Company and its 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).

The General Meeting is presided over by the chairperson of the Board of Directors. If no chairperson has been elected or if he or she is not present at the meeting, the General Meeting shall be presided over by the vice-chairperson of the Board of Directors. If no vice-chairperson has been elected or if he or she is not present at the meeting, the General Meeting shall be presided over by another person designated in accordance with the Articles of Association. Our directors may always attend a General Meeting. In these meetings, they have an advisory vote. The chairperson of the General Meeting may decide at his or her discretion to admit other persons to the meeting.

All shareholders and others with meeting rights under Dutch law are authorized to attend the general meeting, to address the meeting and, insofar as they have such right, to vote pro rata to his or her shareholding. Shareholders may exercise these rights, if they are the holders of shares on the record date, if any, as required by Dutch law, which is currently the 28th day before the day of the general meeting. Under the Articles of Association, shareholders and others with meeting rights under Dutch law must notify us in writing or by electronic means of their identity and intention to attend the General Meeting. This notice must be received by us ultimately on the seventh day prior to the General Meeting, unless indicated otherwise when such meeting is convened.

Each Ordinary Share confers the right on the holder to cast one vote at the General Meeting. Shareholders may vote by proxy. No votes may be cast at a General Meeting on Ordinary Shares held by us or our subsidiaries or on Ordinary Shares for which we or our subsidiaries hold depository receipts. Nonetheless, the holders of a right of usufruct (*vruchtgebruik*) and the holders of a right of pledge (*pandrecht*) in respect of Ordinary Shares held by us or our subsidiaries in its share capital are not excluded from the right to vote on such Ordinary Shares, if the right of usufruct (*vruchtgebruik*) or the right of pledge (*pandrecht*) was granted prior to the time such shares we or any of our subsidiaries acquired. Neither we nor any of our subsidiaries may cast votes in respect of an Ordinary Share on which we or such subsidiary holds a right of usufruct (*vruchtgebruik*) or a right of pledge (*pandrecht*). Ordinary Shares which are not entitled to voting rights pursuant to the preceding sentences will not be taken into account for the purpose of determining the number of shareholders that vote and that are present or represented, or the amount of the share capital that is provided or that is represented at a General Meeting.

Decisions of the General Meeting are taken by a simple majority of votes cast, except where Dutch law or the Articles of Association provide for a qualified majority or unanimity. Subject to any provision of mandatory Dutch law and any higher quorum requirement stipulated by the Articles of Association, if we would be subject to the requirement that the General Meeting can only pass resolutions if a certain part of our issued share capital is present or represented at such General Meeting under applicable securities laws or listing rules, then such resolutions shall be subject to such quorum as specified by such securities laws or listing rules pursuant to the Articles of Association.

Directors

Appointment of Our Directors

Our directors will be appointed by the General Meeting upon binding nomination by the Board of Directors. However, the General Meeting may at all times overrule a binding nomination by a resolution adopted by at least a two-thirds majority of the votes cast, provided such majority represents more than half of our issued share capital. If the General Meeting overrules a binding nomination, the Board of Directors will make a new nomination.

We have adopted a diversity policy for the composition of the Board of Directors, as well as a profile for the composition of the Board of Directors, with the assistance of our nomination and corporate governance committee. The Board of Directors will make any nomination for the appointment of a director with due regard to the rules and principles set forth in such diversity policy and profile, as applicable.

At a General Meeting, a resolution to appoint a director can only be passed in respect of candidates whose names are stated for that purpose in the agenda of that General Meeting or in the explanatory notes thereto.

Duties and Liabilities of Our Directors

Under Dutch law, the Board of Directors is charged with the management of the Company, which includes setting our policies and strategy, subject to the restrictions contained in the Articles of Association. Our executive directors manage our day-to-day business and operations and implement our strategy. Our non-executive directors focus on the supervision on the policy and functioning of the performance of the duties of all of our directors and our general state of affairs. Our directors may divide their tasks among themselves in or pursuant to internal rules. Each of our directors has a statutory duty to act in our corporate interest and our business. Under Dutch law, the corporate interest extends to the interests of all corporate stakeholders, such as shareholders, creditors, employees, customers and suppliers. The duty to act in our corporate interest also applies in the event of a proposed sale or break-up of the Company, provided that the circumstances generally dictate how such duty is to be applied and how the respective interests of various groups of stakeholders should be weighed.

The Board of Directors is entitled to represent us. The power to represent us also vests in our Chief Executive Officer, as well as in any two non-executive directors acting jointly.

Dividends and Other Distributions

Dividends

We have never paid or declared any cash dividends in the past, and we do not anticipate paying any cash dividends in the foreseeable future. We intend to retain all available funds and any future earnings for use in the operation of our business. Under Dutch law, we may only pay dividends and other

distributions from our reserves to the extent our shareholders' equity (*eigen vermogen*) exceeds the sum of its paid-in and called-up share capital plus the reserves We must maintain under Dutch law or the Articles of Association and (if it concerns a distribution of profits) after adoption of our statutory annual accounts by the General Meeting from which it appears that such dividend distribution is allowed.

Under the Articles of Association, the Board of Directors may decide that all or part of the profits shown in our adopted statutory annual accounts will be added to our 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 the 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 Board of Directors. 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*).

Exchange Controls

Under Dutch law, there are no exchange controls applicable to the transfer to persons outside of the Netherlands of dividends or other distributions with respect to, or of the proceeds from the sale of, shares of a Dutch company, subject to applicable restrictions under sanctions and measures, including those concerning export control, pursuant to European Union regulations, the Sanctions Act 1977 (*Sanctiewet 1977*) or other legislation, applicable anti-boycott regulations, applicable anti-money-laundering regulations and similar rules and provided that, under certain circumstances, payments of such dividends or other distributions must be reported to the Dutch Central Bank at their request for statistical purposes. There are no special restrictions in the Articles of Association or Dutch law that limit the right of shareholders who are not citizens or residents of the Netherlands to hold or vote shares.

Squeeze-Out Procedures

A shareholder who holds at least 95% of our issued share capital for his or her own account, alone or together with group companies, may initiate proceedings against us other shareholders jointly for the transfer of their Ordinary Shares to such shareholder. The proceedings are held before the Enterprise Chamber and can be instituted by means of a writ of summons served upon each of the other shareholders in accordance with the provisions of the Dutch Code of Civil Procedure (*Wetboek van Burgerlijke Rechtsvordering*). The Enterprise Chamber may grant the claim for squeeze-out in relation to the other shareholders and will determine the price to be paid for the Ordinary Shares, if necessary, after appointment of one or three experts who will offer an opinion to the Enterprise Chamber on the value to be paid for the Ordinary Shares of the other shareholders. Once the order to transfer becomes final before the Enterprise Chamber, the person acquiring the Ordinary Shares shall give written notice of the date and place of payment and the price to the holders of the Ordinary Shares to be acquired whose addresses are known to him. Unless the addresses of all of them are known to the acquiring person, such person is required to publish the same in a daily newspaper with a national circulation.

Dissolution and Liquidation

Under the Articles of Association, we may be dissolved by a resolution of the General Meeting, subject to a proposal of the Board of Directors. In the event of a dissolution, the liquidation shall be effected by the Board of Directors, unless the General Meeting decides otherwise. During liquidation, the provisions of the Articles of Association will remain in force as far as possible. To the extent that any

assets remain after payment of all of our liabilities, any remaining assets shall be distributed to our shareholders in proportion to their number of Ordinary Shares.

Dutch Corporate Governance Code

Upon the consummation of the Business Combination, we will be subject to the DCGC. The DCGC contains principles and best practice provisions on corporate governance that regulate relations between the board of directors 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. As of the date of this document, our main deviations from the DCGC are summarized below. In the future, we may deviate from additional provisions of the DCGC, including to follow market practice or governance practices in the United States. The DCGC contains certain independence recommendations for the Board of Directors and its committees. We do not comply with all such recommendations.

Under the Articles of Association, our directors are to be appointed on the basis of a binding nomination prepared by the Board of Directors. This means that the nominee will be appointed unless the General Meeting removes the binding nature of the nomination (in which case a new nomination will be prepared for a subsequent General Meeting). The Articles of Association provide that the General Meeting can only pass such resolution by a two-thirds majority representing more than half of the issued share capital. However, the DCGC recommends that the general meeting can pass such a resolution by simple majority, representing no more than one-third of the issued share capital.

Under the Articles of Association, our directors can only be dismissed by the General Meeting by simple majority, provided that the Board of Directors proposes the dismissal. In other cases, the General Meeting can only pass such resolution by a two-thirds majority representing more than half of the issued share capital. The DCGC recommends that the general meeting can pass a resolution to dismiss a director by simple majority, representing no more than one-third of the issued share capital.

The DCGC recommends against providing equity awards as part of the compensation of a non-executive director. However, we may deviate from this recommendation and grant equity awards to our non-executive directors, consistent with U.S. market practice.

As part of the compensation of our directors, we may grant shares that are not subject to a lock-up period of at least five years after the date of grant and/or grant options without restricting the exercisability of those options during the first three years after the date of grant. In those cases, this would cause additional deviations from the DCGC.

Dutch Financial Reporting Supervision Act

On the basis of the Dutch Financial Reporting Supervision Act (*Wet toezicht financiële verslaggeving*), or the FRSA, the Dutch Authority for the Financial Markets (*Stichting Autoriteit Financiële Markten*) (“AFM”), supervises the application of financial reporting standards by Dutch companies whose securities are listed on a Dutch or foreign stock exchange.

Pursuant to the FRSA, the AFM has an independent right to (i) request an explanation from us regarding our application of the applicable financial reporting standards if, based on publicly known facts or circumstances, it has reason to doubt that our financial reporting meets such standards and (ii)

recommend to us the making available of further explanations. If we do not comply with such a request or recommendation, the AFM may request that the Enterprise Chamber order us to (i) make available further explanations as recommended by the AFM, (ii) provide an explanation of the way we have applied the applicable financial reporting standards to our financial reports or (iii) prepare or restate our financial reports in accordance with the Enterprise Chamber's orders.

Transfer Agent and Registrar

The transfer agent and registrar for the Ordinary Shares is Continental Stock Transfer & Trust Company.

**CERTIFICATION 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**

I, Michael Davidson, M.D., certify that:

1. I have reviewed this annual report on Form 20-F/A of NewAmsterdam Pharma Company N.V.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: October 28, 2024

By: /s/ Michael Davidson

Michael Davidson, M.D.

Chief Executive Officer

**CERTIFICATION 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**

I, Ian Somaiya, certify that:

1. I have reviewed this annual report on Form 20-F/A of NewAmsterdam Pharma Company N.V.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: October 28, 2024

By: /s/ Ian Somaiya

Ian Somaiya

Chief Financial Officer

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

The certification set forth below is being submitted in connection with the Annual Report on Form 20-F/A for the year ended December 31, 2022 (the "Report") for the purpose of complying with Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code.

I, Michael Davidson, M.D., certify that:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: October 28, 2024

By: /s/ Michael Davidson

Michael Davidson, M.D.

Chief Executive Officer

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

The certification set forth below is being submitted in connection with the Annual Report on Form 20-F/A for the year ended December 31, 2022 (the "Report") for the purpose of complying with Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code.

I, Ian Somaiya, certify that:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: October 28, 2024

By: /s/ Ian Somaiya

Ian Somaiya

Chief Financial Officer
