UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2024

OR

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

For the transition period from to

Commission File Number: 001-41562

NewAmsterdam Pharma Company N.V.
(Exact Name of Registrant as Specified in its Charter)

The Netherlands	**N/A**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
Gooimeer 2-35	
Naarden	
The Netherlands	**1411 DC**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: +31 (0) 35 206 2971

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

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

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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☒		

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

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

As of October 31, 2024, the registrant had 92,385,872 ordinary shares, nominal value €0.12 per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q ("Quarterly Report") contains forward-looking statements. Forward-looking statements provide the Company's current expectations or forecasts of future events. Forward-looking statements include statements about the Company's expectations, beliefs, plans, objectives, intentions, assumptions and other statements that are not historical facts. Words or phrases such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "will" and "would," or similar words or phrases, or the negatives of those words or phrases, may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. Examples of forward-looking statements in this Quarterly Report include, but are not limited to, statements regarding the Company's disclosure concerning its operations, cash flows, financial position and dividend policy.

Forward-looking statements in this Quarterly Report and in any document incorporated by reference in this Quarterly Report may include, for example, statements about:

- the potential liquidity and trading of the Company's public securities;
- the Company's ability to raise additional capital in sufficient amounts or on terms acceptable to it;
- the efficacy and safety of the Company's product candidate, obicetrapib, as well as potential reimbursement and anticipated market size and market opportunity;
- the Company's dependence on the success of obicetrapib, including the obtaining of regulatory approval to market obicetrapib;
- the timing, progress and results of clinical trials for obicetrapib, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work and the period during which results of trials will become available and marketing submissions made;
- the Company's ability to attract and retain senior management and key scientific personnel;
- the Company's limited experience in marketing or distributing products;
- managing the risks related to the Company's international operations;
- the Company's ability to achieve the broad degree of physician adoption and use and market acceptance necessary for commercial success;
- the Company's estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- developments regarding the Company's competitors and the Company's industry;
- the impact of government laws and regulations;
- the Company's reliance on third parties for all aspects of the manufacturing of obicetrapib for clinical trials; and
- the Company's efforts to obtain, protect or enforce its patents and other intellectual property rights related to the Company's product candidate.

Forward-looking statements are subject to known and unknown risks and uncertainties and are based on potentially inaccurate assumptions that could cause actual results to differ materially from those expected or implied by the forward-looking statements. Actual results could differ materially from those anticipated in forward-looking statements for many reasons, including the factors described in the section titled "*Risk Factors*" in this Quarterly Report. Accordingly, you should not place undue reliance on these forward-looking statements, which speak only as of the date of this Quarterly Report. The Company undertakes no obligation to publicly revise any forward-looking statement to reflect circumstances or events after the date of this Quarterly Report or to reflect the occurrence of unanticipated events, except as specifically required by law. You should, however, review the factors and risks that the Company describes in the reports it files from time to time with the U.S. Securities and Exchange Commission (the "SEC").

In addition, statements that "we believe" and similar statements reflect the Company's beliefs and opinions on the relevant subject. These statements are based on information available to the Company as of the date of this Quarterly Report. And while the Company believes that information provides a reasonable basis for these statements, that information may be limited or incomplete. The Company's statements should not be read to indicate that it has conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely on these statements.

Although the Company believes the expectations reflected in the forward-looking statements were reasonable at the time made, it cannot guarantee future results, level of activity, performance or achievements. You should carefully consider the cautionary statements contained or referred to in this section in connection with the forward-looking statements contained in this Quarterly Report and any subsequent written or oral forward-looking statements that may be issued by the Company or persons acting on its behalf.

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

SUMMARY OF SELECTED RISKS ASSOCIATED WITH OUR BUSINESS

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

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

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

Risks Related to Our Product Development, Regulatory Approval and Commercialization

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

Risks Related to Our Business and Strategy

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

Risks Related to Our Intellectual Property

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

that we are unaware of prior art that may affect the validity of our patents, we may not be able to compete effectively in our market and we otherwise may be harmed.

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

Risks Related to Ownership of Our Securities

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

•We 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.

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

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

NewAmsterdam Pharma Company N.V.
Condensed Consolidated Balance Sheets
(Unaudited)

(In thousands of USD)	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash	422,729	340,450
Prepayments and other receivables	15,145	6,341
Total current assets	437,874	346,791
Property, plant and equipment, net	231	46
Operating right of use asset	493	55
Intangible assets	593	170
Long term prepaid expenses	-	35
Total assets	439,191	347,097
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	7,039	16,923
Accrued expenses and other current liabilities	10,580	11,398
Deferred revenue, current	4,495	8,942
Lease liability, current	240	60
Derivative warrant liabilities	18,901	12,574
Total current liabilities	41,255	49,897
Deferred revenue, net of current portion	-	1,019
Lease liability, net of current portion	266	-
Derivative earnout liability	18,808	7,788
Total liabilities	60,329	58,704
Commitments and contingencies (Note 10)		
Shareholders' Equity (deficit):		
Ordinary shares, €0.12 par value; 400,000,000 shares authorized; 92,165,605 and 82,469,768 shares issued and outstanding as at September 30, 2024 and December 31, 2023, respectively	11,435	10,173
Additional paid-in capital	829,399	590,771
Accumulated loss	(466,394)	(316,973)
Accumulated other comprehensive income	4,422	4,422
Total shareholders' equity	378,862	288,393
Total liabilities and shareholders' equity	439,191	347,097

See notes to consolidated financial statements.

NewAmsterdam Pharma Company N.V.
Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)
(Unaudited)

	For the three months ended September 30,		For the nine months ended September 30,	
	2024	**2023**	**2024**	**2023**
(In thousands of USD, except per share amounts)				
Revenue	29,111	2,941	32,791	13,287
Operating expenses:				
Research and development expenses	35,702	43,371	116,511	118,132
Selling, general and administrative expenses	18,412	9,128	49,340	27,048
Total operating expenses	54,114	52,499	165,851	145,180
Operating loss	(25,003)	(49,558)	(133,060)	(131,893)
Other income (expense):				
Interest income	4,443	3,059	12,396	8,615
Fair value change – earnout and warrants	(770)	2,521	(30,028)	(4,004)
Foreign exchange gains/(losses)	4,682	(3,155)	1,270	(160)
Loss before tax	(16,648)	(47,133)	(149,422)	(127,442)
Income tax expense	(1)	—	(1)	—
Loss and comprehensive loss for the period	(16,647)	(47,133)	(149,421)	(127,442)
Net loss per ordinary share				
Basic and diluted	$ (0.18)	$ (0.57)	$ (1.61)	$ (1.55)

See notes to consolidated financial statements.

NewAmsterdam Pharma Company N.V.
Condensed Consolidated Statements of Shareholders' Equity (Deficit)
(Unaudited)

(In thousands of USD, except share amounts)	Shares	Amount	Additional Paid-In Capital	Accumulated Loss	Cumulative Translation Adjustments	Total Shareholder s' Equity
Balance at December 31, 2022	81,559,780	10,055	555,625	(140,036)	4,422	430,066
Exercise of warrants	208,032	27	2,671	—	—	2,698
Share-based compensation	—	—	7,663	—	—	7,663
Total loss and comprehensive loss for the period	—	—	—	(42,018)	—	(42,018)
As at March 31, 2023	81,767,812	10,082	565,959	(182,054)	4,422	398,409
Exercise of warrants	541,609	70	7,444	—	—	7,514
Exercise of stock options	14,910	2	103	—	—	105
Share-based compensation	—	—	5,606	—	—	5,606
Total loss and comprehensive loss for the period	—	—	—	(38,291)	—	(38,291)
As at June 30, 2023	82,324,331	10,154	579,112	(220,345)	4,422	373,343
Exercise of warrants	100	0	1	—	—	1
Exercise of stock options	145,337	19	166	—	—	185
Share-based compensation	—	—	5,439	—	—	5,439
Total loss and comprehensive loss for the period	—	—	—	(47,133)	—	(47,133)
As at September 30, 2023	82,469,768	10,173	584,718	(267,478)	4,422	331,835
Balance at December 31, 2023	82,469,768	10,173	590,771	(316,973)	4,422	288,393
Issuance of Ordinary Shares and Pre-Funded Warrants, net of issuance costs	5,871,909	759	189,207	—	—	189,966
Exercise of warrants	926,698	121	19,674	—	—	19,795
Exercise of stock options	452,461	60	(609)	—	—	(549)
Share-based compensation	—	—	7,965	—	—	7,965
Total loss and comprehensive loss for the period	—	—	—	(93,767)	—	(93,767)
As at March 31, 2024	89,720,836	11,113	807,008	(410,740)	4,422	411,803
Exercise of warrants	294,521	38	6,268	—	—	6,306
Share-based compensation	—	—	8,337	—	—	8,337
Total loss and comprehensive loss for the period	—	—	—	(39,007)	—	(39,007)
As at June 30, 2024	90,015,357	11,151	821,613	(449,747)	4,422	387,439
Exercise of Pre-Funded Warrants	2,105,248	279	(279)	—	—	—
Exercise of stock options	45,000	5	53	—	—	58
Share-based compensation	—	—	8,012	—	—	8,012
Total loss and comprehensive loss for the period	—	—	—	(16,647)	—	(16,647)
As at September 30, 2024	92,165,605	11,435	829,399	(466,394)	4,422	378,862

See notes to consolidated financial statements.

NewAmsterdam Pharma Company N.V.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	For the nine months ended September 30,	
	2024	**2023**
(In thousands of USD)		
Operating activities:		
Loss for the period	(149,421)	(127,442)
Non-cash adjustments to reconcile loss before tax to net cash flows:		
Depreciation and amortization	62	36
Non-cash rent expense	8	5
Fair value change - derivative earnout and warrants	30,028	4,004
Foreign exchange (gains)/losses	(1,270)	160
Share-based compensation	24,204	18,566
Changes in working capital:		
Changes in prepayments (current and non-current) and other receivables	(8,769)	988
Changes in accounts payable	(9,751)	(7,824)
Changes in accrued expenses and other current liabilities	(708)	11,266
Changes in deferred revenue	(5,466)	(7,903)
Net cash (used in)/provided by operating activities	**(121,083)**	**(108,144)**
Investing activities:		
Purchase of property, plant and equipment, including internal use software	(669)	(21)
Net cash used in investing activities	**(669)**	**(21)**
Financing activities:		
Proceeds from offering of Ordinary Shares and Pre-Funded Warrants	190,481	—
Transaction costs on issue of Ordinary Shares and Pre-Funded Warrants	(515)	—
Proceeds from exercise of warrants	13,421	8,622
Proceeds from exercise of options	498	290
Payment of withholding taxes related to net share settlement of exercised options	(989)	—
Net cash provided by financing activities	**202,896**	**8,912**
Net change in cash	81,144	(99,253)
Foreign exchange differences	1,135	(168)
Cash at the beginning of the period	340,450	467,728
Cash at the end of the period	**422,729**	**368,307**
Noncash financing and investing activities		
Right-of-use assets obtained in exchange for new operating lease liabilities	562	—

See notes to consolidated financial statements

NewAmsterdam Pharma Company N.V.
Notes to Unaudited Condensed Consolidated Financial Statements

Note 1. The Company

NewAmsterdam Pharma Company N.V. ("NewAmsterdam Pharma" or the "Company") is a late-stage biopharmaceutical company whose mission is to improve patient care in populations with metabolic diseases where currently approved therapies have not been adequate or well-tolerated. The Company was incorporated in the Netherlands as a Dutch private company with limited liability (besloten vennootschap met beperkte aansprakelijkheid) under the name NewAmsterdam Pharma Company B.V. on June 10, 2022. On November 21, 2022, the Company's corporate form was converted to a Dutch public limited liability company (naamloze vennootschap) and its name was changed to NewAmsterdam Pharma Company N.V. The Company's ordinary shares, nominal value €0.12 per share (the "Ordinary Shares") are listed on the Nasdaq Global Market ("Nasdaq") and trade under the symbol "NAMS."

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

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited condensed consolidated financial statements should be read together with the Company's audited financial statements and accompanying notes for year ended December 31, 2023, included in the Company's Annual Report on Form 10-K (the "Annual Report"), filed with the SEC on February 28, 2024. Any terms not defined herein take the meaning as defined in the Annual Report. The Company's unaudited condensed consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") and the rules and regulations of the U.S. Securities and Exchange Commission ("SEC") regarding interim financial reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP have been condensed or omitted, and accordingly the balance sheet as of December 31, 2023 included herein has been derived from the audited financial statements at that date but does not include all of the information required by U.S. GAAP for complete financial statements. These unaudited interim condensed consolidated financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments which are necessary for a fair statement of the Company's financial information. The interim results of operations for the three and nine months ended September 30, 2024 are not necessarily indicative of the results to be expected for the year ending December 31, 2024 or for any other interim period or for any other future year. The unaudited condensed consolidated financial statements comprise the financial statements of the Company and its subsidiaries. Any reference in these notes to the applicable guidance is meant to refer to authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB"). The unaudited condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, after elimination of intercompany accounts and transactions.

Prior to 2023, the Company prepared its financial statements in accordance with the International Financial Reporting Standards as issued by the International Accounting Standard Board ("IFRS") as permitted in the United States based on the Company's qualification as a foreign private issuer under the rules and regulations of the SEC. In connection with the loss of the Company's status as a foreign private issuer effective on January 1, 2024, the Company, as a domestic filer, prepared these financial statements in accordance with U.S. GAAP. The transition to U.S. GAAP was made retrospectively for all periods from the Company's inception.

Except for the policy described below, the accounting policies of the Company are consistent with those described in Note 2 of the consolidated financial statements included within the Annual Report.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of Ordinary Shares outstanding during the period. For the purposes of calculating the weighted-average number of Ordinary Shares outstanding, the Ordinary Shares underlying the Pre-Funded Warrants issued in the Offering (as defined in Note 7 below) are included. Diluted net loss per share is the same as basic net loss per share, since the effects of potentially dilutive securities are antidilutive given the net loss for each period presented.

Note 3. Revenue

Revenue consisted of the following:

	Three months ended September 30,		Nine months ended September 30,	
(In thousands of USD)	2024	2023	2024	2023
License revenue attributed from license performance obligation	27,325	—	27,325	5,385
License revenue attributed from R&D performance obligation	1,786	2,941	5,466	7,902
Total revenue	29,111	2,941	32,791	13,287

All revenue recognized from the R&D performance obligation was included within deferred revenue on the consolidated balance sheet as of the beginning of the applicable reporting period.

Note 4. Fair Value Measurements

As at September 30, 2024 and December 31, 2023, the Company's financial liabilities recognized at fair value on a recurring basis consisted of the following:

	As at September 30, 2024			
(In thousands of USD)	Level 1	Level 2	Level 3	Total
Derivative warrant liability (Public Warrants)	17,732	—	—	17,732
Derivative warrant liability (Private Placement Warrants)	—	1,169	—	1,169
Derivative earnout liability	—	—	18,808	18,808
Total financial liabilities	17,732	1,169	18,808	37,709

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

The estimated fair value of the derivative earnout liability 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 derivative earnout liability has been measured at fair value using a Black-Scholes pricing model. Given the assumed zero dividend rate and the fact that no strike price exists that would have led to any volatility measure relative to the Company's share price, the fair value of the earnout liability resulting from the Black-Scholes pricing model is entirely driven by the Company's closing share price as a Level 1 input and the probability of milestone completion as a Level 3 input. As such, the relevant inputs to the fair value of the derivative earnout liability are as follows:

	September 30, 2024	December 31, 2023
Ordinary Share value (USD)	$ 16.60	$ 11.17
Probability of milestone completion	65%	40%
Dividend yield	0%	0%
Strike price (USD)	0.00	0.00

On July 29, 2024 the Company announced positive topline results from its Phase 3 BROOKLYN clinical trial. Positive results from the BROOKLYN trial is a component of the milestone which is required in order for the Earnout Shares to be granted. The Company has determined that the reporting of positive data from the BROOKLYN clinical trial increases the probability of achieving the milestone from 40% to 65%. The change in fair value results from the increase in the probability of achieving the milestone, a Level 3 input, and the change in the Company's Ordinary Share value between valuation dates.

The following table presents a reconciliation of the derivative earnout liability measured on a recurring basis using Level 3 inputs as of September 30, 2024:

Balance on December 31, 2023	7,788
Change in fair value recognized through profit and loss	11,020
Balance on September 30, 2024	18,808

All changes in fair value recognized in the statement of operations are unrealized. There were no sales, purchases, settlements or transfers into or out of Level 3 of the fair value hierarchy related to the derivative earnout liability during the period ended September 30, 2024.

Note 5. Prepayments and Other Receivables

Prepayments and other receivables consisted of the following:

(In thousands of USD)	September 30, 2024	December 31, 2023
Prepaid research and development costs	8,830	2,337
Other prepaid expenses	1,169	2,123
Value added tax receivable	3,500	1,006
Other receivables	1,646	875
Total prepayments and other receivables	15,145	6,341

Note 6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

(in thousands of USD)	September 30, 2024	December 31, 2023
Accrued research and development materials and services	3,863	5,945
Accrued compensation and benefits	4,188	3,384
Accrued professional fees and other	2,529	2,069
Total accrued expenses and other current liabilities	10,580	11,398

Note 7. Shareholders' Equity

Follow-on Offering

On February 16, 2024, the Company completed an underwritten public offering (the "Offering") of 5,871,909 Ordinary Shares at a public offering price of $19.00 per Ordinary Share and, in lieu of Ordinary Shares to certain investors, pre-funded warrants (the "Pre-Funded Warrants") to purchase 4,736,841 Ordinary Shares at a public offering price of $18.9999 per Pre-Funded Warrant, which represents the per share public offering price for the Ordinary Shares, less the $0.0001 per share exercise price for each such Pre-Funded Warrant. Of the 5,871,909 Ordinary Shares issued and sold in the offering, 1,383,750 Ordinary Shares were issued and sold pursuant to the exercise of the underwriters' option to purchase additional Ordinary Shares at the public offering price per share. The Ordinary Shares and Pre-Funded Warrants were issued and sold pursuant to an underwriting agreement, among the Company and Jefferies LLC, Leerink Partners LLC, Piper Sandler & Co. and RBC Capital Markets, LLC, as representatives of the several underwriters listed on Schedule A thereto. The net proceeds to the Company from the Offering were $190.0 million after deducting underwriting discounts and commissions and offering expenses payable by the Company. During the period from the date of the Offering to September 30, 2024 a total of 2,105,263 Pre-Funded Warrants were exercised resulting in the issuance of 2,105,248 Ordinary Shares.

Note 8. Share-Based Compensation

The Company has four share-based payment plans and one restricted share award in place as at September 30, 2024:

- The Company's Long-Term Incentive Plan (the "Plan");
- The Company's Supplementary Long-Term Incentive Plan (the "Supplementary Plan");
- The Company's Rollover Option Plan (the "Rollover Plan,");
- The Company's Inducement Plan (the "Inducement Plan," together with the Plan, the Supplementary Plan and the Rollover Plan, the "Plans"); and

•Chief Executive Officer Restricted Share Award.

The Plans

The Plans are equity-settled, and the Company may grant various forms of equity awards, including the granting of options to purchase Ordinary Shares ("Company Options") and restricted stock units ("RSUs"), pursuant to the Plans. In total, as of September 30, 2024 a maximum of 22,049,356 Ordinary Shares may be reserved for issuance pursuant to the Plans. The number of Ordinary Shares reserved for grant under the Plan will increase annually on January 1 of each calendar year by 5% of the then issued and outstanding Ordinary Shares or such lower number as may be determined by the Company's Board of Directors.

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

Modification of Options During the Period

In 2024, a total of 399,153 Company Options granted to one employee were modified. For 210,655 of the modified Company Options the vesting period was shortened, of which 200,655 such modified Company Options also had the exercise period extended. For the other 188,498 modified Company Options only the exercise period was extended.

The total fair value of the 210,655 modified Company Options for which the vesting period was shortened is equal to $1.2 million. Any expense previously recognized for such Company Options was reversed on the modification date and the full fair value of the modified Company Options is recognized over the applicable service period. For the 188,498 modified Company Options for which only the exercise period was extended the total fair value of the modification is equal to $0.1 million, all of which is recognized on the modification date.

The changes for the nine months ended September 30, 2023 in the number of Company Options outstanding related to Ordinary Shares and their related weighted average exercise prices are as follows:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (in years)	Aggregate intrinsic value (in thousands of USD)
Outstanding as at December 31, 2023	15,783,509	$ 7.98		
Granted	4,988,848	$ 14.06		
Exercised	(591,403)	$ 1.27		
Forfeited	—	$ -		
Outstanding as at September 30, 2024	20,180,954	$ 9.68	8.3	145,756
Options exercisable as at September 30, 2024	7,820,112	$ 6.49	7.6	79,035

The weighted average grant date fair value of Company Options, estimated as of the grant date using the Black-Scholes option pricing model, was $6.60, and $4.83 per option for options granted during the nine months ended September 30, 2024 and 2023, respectively. The total intrinsic value (the amount by which the fair market value exceeded the exercise price) of Company Options exercised during the nine months ended September 30, 2024 and 2023 was $8.7 million and $1.7 million, respectively. Weighted average assumptions used to apply this pricing model were as follows:

	Nine months ended September 30,	
	2024	2023
Expected life (years)	6.1	6.1
Risk-free rate	3.9%	4.0%
Volatility	41.7%	38.3%
Dividend yield	0.0%	0.0%

Expected Term

The Company's expected term represents the period that the Company's stock-based awards are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term). The Company utilizes this method due to lack of historical exercise data and the plain-vanilla nature of the Company's stock-based awards.

Expected Volatility

Since the Company was privately held through November 2022, it alone does not have sufficient relevant company-specific historical data to support its expected volatility alone. In prior periods, due to the insufficiency of historical volatility data on the Company's own securities, the expected volatility input was determined using comparable companies alone. Beginning on January 1, 2024 expected volatility input was determined using a weighted average calculation considering the volatility of the Company's own securities and the volatilities of a representative group of publicly traded biopharmaceutical companies over a period equal to the expected term of the stock option grants. Initially, the volatility of the Company's Ordinary Shares is assigned a weighting of 10%. This weighting will be increased by 5% per calendar quarter until the expected volatility input is based entirely on the historical volatility of the Company's Ordinary Shares. For purposes of identifying comparable companies, the Company selected companies with comparable characteristics to it, including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards.

Risk-Free Interest Rate

The risk-free interest rate is based upon the U.S. Treasury yield curve in effect at the time of grant, with a term that approximates the expected life of the Company Option.

Expected Dividend

The expected dividend rate is zero as the Company currently has no history or expectation of declaring dividends on its Ordinary Shares.

Share-based compensation is classified in the consolidated statement of operations and comprehensive loss as follows:

	Three months ended September 30,		Nine months ended September 30,	
(in thousands of USD)	**2024**	**2023**	**2024**	**2023**
Research and development expenses	3,043	3,273	9,514	11,492
Selling, general and administrative expenses	4,953	2,119	14,690	7,074
Total	7,996	5,392	24,204	18,566

As of September 30, 2024, there was $33.4 million of unrecognized compensation cost related to Company Options that have not yet vested. These costs are expected to be recognized over a weighted average period of 3.0 years until fully vested.

Restricted Stock Units

As at September 30, 2024 and December 31, 2023, the Company had allocated 143,002 Earnout Shares to be granted to Participating Optionholders if and when a certain clinical development milestone is achieved during the earnout period. These Earnout Shares will be delivered in the form of awards of RSUs granted pursuant to the Plan to such Participating Optionholders who are at the time of achievement of such milestone still providing services to the Company.

The development milestone consists of the achievement and public announcement of positive Phase 3 data for each of the Company's BROADWAY clinical trial and BROOKLYN clinical trial at any time during the period beginning on November 22, 2022 and ending on the date that is five years after such date.

There is no impact on these financial statements with respect to these RSUs due to the uncertainty of achieving the clinical development milestone.

Chief Executive Officer Restricted Share Award

In July 2021, the Company's chief executive officer, Michael Davidson, M.D., paid the fair market value of the underlying Ordinary Shares (in aggregate $838,806) when he made an investment in restricted shares issued through Depositary Receipts. The total fair value of these equity-settled share-based payment awards amounts to nil and there will be no expenses recognized in the income statement. This award had a four year vesting period with 25% vesting on August 1, 2021 and the remaining 75% vesting in equal monthly installments over the following three years.

In connection with the award arrangement, if Dr. Davidson leaves the Company, all unvested Ordinary Shares will be cancelled against payment by the Company to him of the lower of the (i) the purchase price paid and (ii) the fair market value of such Ordinary Shares at the time of forfeiture. In order to reflect the consideration paid and the possibility that the Ordinary Shares would be repurchased if Dr. Davidson becomes a "Good Leaver" (as such term is defined in the award agreement) during the vesting period, the Company has recognized the consideration as a financial liability until the award has fully vested, at which time it will be reclassified to equity provided that Dr. Davidson remains with the Company. This liability is measured at the lower of (i) the purchase price paid and (ii) the fair market value of the Ordinary

Shares at the end of the reporting period. The liability for unvested Ordinary Shares as at September 30, 2024 and December 31, 2023 amounted to nil and $0.1 million, respectively.

For the nine months ended September 30, 2024, the movements in the number of Ordinary Shares outstanding are as follows:

Outstanding as at December 31, 2023	608,779
Granted/purchased during the period	—
Outstanding as at September 30, 2024	608,779

As of September 30, 2024 and December 31, 2023, a total of 608,779 and 519,999 Ordinary Shares had vested, respectively.

Note 9. Net Loss per Ordinary Share

For the purposes of calculating the weighted-average number of Ordinary Shares outstanding, the Ordinary Shares underlying the Pre-Funded Warrants issued in the Offering are included.

Basic and diluted net loss per Ordinary Share was calculated as follows:

	Three months ended September 30,		Nine months ended September 30,	
(In thousands of USD, except share and per share amounts)	2024	2023	2024	2023
Net loss	(16,647)	(47,133)	(149,421)	(127,442)
Weighted average Ordinary Shares outstanding, basic and diluted	94,754,140	82,466,584	92,666,874	82,058,225
Net loss per Ordinary Share, basic and diluted	(0.18)	(0.57)	(1.61)	(1.55)

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average Ordinary Shares outstanding as they would be anti-dilutive:

	As at September 30,	
	2024	2023
Stock options	20,180,954	14,751,425
Outstanding warrants	2,700,152	4,017,221
Total	22,881,106	18,768,646

Note 10. Commitments and Contingencies

Commitments

The Company has entered into a variety of agreements and financial commitments in the normal course of business with contract research organizations, contract manufacturing organizations, and other third parties for preclinical and clinical development and manufacturing services. The terms generally provide the Company with the option to cancel, reschedule and adjust our requirements based on the Company's business needs, prior to the delivery of goods or performance of services. Payments due upon cancellation generally consist only of payments for services provided or expenses incurred, including non-cancellable obligations of the Company's service providers, up to the date of cancellation. However, some of the Company's service providers also charge cancellation fees upon cancellation. The amount and timing of such payments are not known, but at September 30, 2024 they are estimated to be a maximum of $16.7 million.

According to the terms of the Menarini License the Company will be responsible for development and commercialization costs related to Licensed Products other than those in the Menarini Territory. In addition, under specified conditions of the agreement, the Company agreed to bear 50% of certain development costs incurred by the other party in the development of the Licensed Products in the Menarini Territory.

Note 11. Related Parties

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

Note 12. Subsequent Events

None.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The unaudited condensed consolidated financial statements, included elsewhere in this Quarterly Report, and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read together with our audited financial statements and accompanying notes for year ended December 31, 2023, included in our Annual Report on Form 10-K (the "Annual Report"), filed with the SEC on February 28, 2024, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations. In addition to historical financial information, the following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those contained in or implied by any forward-looking statements. Factors that could cause or contribute to these differences include those discussed in the sections titled "Risk Factors" and "Special Note Regarding Forward-Looking Statements" in the Annual Report and this Quarterly Report. Our operating results are not necessarily indicative of results that may occur for the full fiscal year or any other future period.

Overview

We are a late-stage biopharmaceutical company whose mission is to improve patient care in populations with metabolic diseases where currently approved therapies have not been adequate or well tolerated. We seek to fill a significant unmet need for a safe, well tolerated and convenient low-density lipoprotein cholesterol ("LDL-C") lowering therapy. In multiple phase 3 studies, we are investigating obicetrapib, an oral, low-dose and once-daily cholesteryl ester transfer protein ("CETP") inhibitor, alone or as a fixed-dose combination with ezetimibe, as preferred LDL-C lowering therapies to be used as an adjunct to statin therapy for patients at risk of cardiovascular disease with elevated LDL-C, for whom existing therapies are not sufficiently effective or well tolerated. We believe that CETP inhibition may also play a role in other indications by potentially mitigating the risk of developing diseases such as Alzheimer's disease or Type 2 diabetes.

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-C 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 2 ROSE2 clinical trial evaluating obicetrapib in combination with ezetimibe as an adjunct to high-intensity statin therapy, obicetrapib met its primary and secondary endpoints, with statistically significant reductions in LDL-C and apolipoprotein observed. In our Phase 2 and Phase 3 trials, TULIP, ROSE, OCEAN, ROSE2, our Japan Phase 2b trial and BROOKLYN evaluating obicetrapib as a monotherapy or a combination therapy with ezetimibe 10 mg, we observed statistically significant LDL-C lowering with side effects similar in frequency and severity to placebo including muscle related side effects and drug-related treatment-emergent serious adverse events. We have observed a favorable tolerability profile for obicetrapib in an aggregate of over 800 patients with dyslipidemia in our clinical trials to date. Furthermore, we believe that obicetrapib's oral delivery, demonstrated activity at low doses, chemical properties and tolerability make it well-suited for combination approaches. We are developing a fixed dose combination of obicetrapib 10 mg and ezetimibe 10 mg, which has been observed to demonstrate even greater LDL-C reduction in our Phase 2b ROSE2 clinical trial.

Lowering of LDL-C, has been associated with major adverse cardiovascular events ("MACE") benefit in trials of LDL-C lowering drugs, including the REVEAL trial with the CETP inhibitor, anacetrapib. We are performing a cardiovascular outcomes trial ("CVOT") to reconfirm this relationship.

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

We have partnered with Menarini, providing them with the exclusive rights to commercialize obicetrapib 10 mg either as a sole active ingredient product or in a fixed dose combination with ezetimibe in the majority of European countries, if approved. Subject to receipt of marketing approval, our current plan is to pursue development and commercialization of obicetrapib in the United States ourselves, and to consider additional partners for jurisdictions outside of the United States and the European Union (the "EU"), including in Japan and China. In addition to our partnership with Menarini, we may in the future utilize a variety of types of collaboration, license,

monetization, distribution and other arrangements with other third parties relating to the development or commercialization, once approved, of obicetrapib or future product candidates or indications. We are also continually evaluating the potential acquisition or license of new product candidates.

As of September 30, 2024 we had cash of $422.7 million as compared to $340.5 million as of December 31, 2023. The increase in cash is primarily driven by the proceeds of the Offering (as defined below), Warrant (as defined below) exercises and the achievement of a clinical development milestone partially offset by cash outflows related to research and development costs as we continue development of obicetrapib and increased spending on selling, general and administrative expenses to support our growing organization. While we currently qualify as an "emerging growth company," we will no longer qualify as such as of December 31, 2024 and, as a result, we will no longer be able to avail ourselves of certain reduced reporting requirements applicable to emerging growth companies and expect to incur increased expenses as a result.

Recent Developments

TANDEM Enrollment

On July 8, 2024, we announced the completion of patient enrollment in the pivotal Phase 3 TANDEM clinical trial evaluating the fixed-dose combination ("FDC") of obicetrapib plus ezetimibe in adult patients with HeFH and/or ASCVD or multiple risk factors for ASCVD, whose LDL-C is not adequately controlled despite being on maximally tolerated lipid-modifying therapies. The co-primary endpoints of the placebo-controlled, double-blind, four-arm, randomized TANDEM trial evaluate the effect of the FDC of 10 mg obicetrapib and 10 mg ezetimibe on the change in LDL-C levels from baseline, compared to ezetimibe 10 mg monotherapy, to obicetrapib 10 mg monotherapy and to placebo. A fourth co-primary endpoint was added to evaluate the effect of 10 mg obicetrapib monotherapy compared to placebo. Secondary endpoints include evaluating the percent change from baseline of the FDC on lipoprotein(a), apolipoprotein B and non-high-density lipoprotein cholesterol. The trial will also evaluate the safety and tolerability profile of the FDC. We expect to report topline data in the fourth quarter of 2024.

Positive Topline Data from Pivotal Phase 3 BROOKLYN Clinical Trial

On July 29, 2024, we announced positive topline data from our Phase 3 BROOKLYN clinical trial (NCT05425745). The BROOKLYN trial met its primary endpoint, with the obicetrapib arm achieving a statistically significant reduction of LDL-C versus placebo at day 84. An LS mean reduction of 36.3% ($p < 0.0001$) was observed compared to placebo at day 84, which was sustained at day 365 with an LS mean LDL-C reduction of 41.5% ($p < 0.0001$). The observed reductions in other biomarkers, including high-density lipoprotein cholesterol ("HDL-C"), non-HDL-C, lipoprotein(a), and apolipoprotein B, met statistical significance.

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 $120.9 million (€115.0 million) from Menarini on July 7, 2022, of which $98.6 million (€93.5 million) was recognized as revenue upon the execution of the Menarini License on June 23, 2022 and $4.1 million (€4.0 million) was subsequently recognized as revenue in 2022. In the three and nine months ended September 30, 2024, $1.8 million and $5.5 million of revenue was recognized, respectively, related to the recognition of additional amounts of the deferred portion of the upfront payment received from Menarini. Additionally, in partial contribution to our costs of development of the licensed products, Menarini may pay us €27.5 million, payable in two equal annual installments. Due to the scientific uncertainties around the commercialization of the licensed products based on the success of clinical trials, 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 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. At the end of each reporting period, we assess the probability of significant reversals for any amounts that become likely to be realized prior to recognizing the variable consideration associated with these payments within the transaction price.

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

Research and Development Expenses

Research and development expenses are recognized as an expense when incurred and are typically made up of costs from our clinical and preclinical activities, drug development and manufacturing costs, and costs for contract research organizations ("CROs") and investigative sites. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data provided by vendors of their actual costs incurred. At each balance sheet date, we estimate the level of services provided by vendors and the associated expenditure incurred for the services performed.

All such costs are for the purpose of advancing our product candidate to successfully complete clinical development, attain regulatory approval and, if approved, commercialize our product candidate. Much of our current focus in our ongoing Phase 3 trials is on patient recruitment and retention and data cleaning. Research and development expenses consist of the following:

- clinical expenses primarily incurred by CROs assisting with our sponsored clinical trials and including clinical investigator costs, patient enrollments and costs of clinical sites;
- manufacturing expenses arising from active pharmaceutical ingredient and drug product development as performed by our contract manufacturing organizations ("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 be significant as we advance obicetrapib through clinical trials and pursue regulatory approval. The process of conducting the necessary clinical trials to obtain regulatory approval is costly and time-consuming. Clinical trials generally become larger and more costly to conduct as they advance into later stages and, in the future, we will be required to make estimates for expense accruals related to clinical trial expenses. At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of obicetrapib. See the section entitled "*Risk Factors—Risks Related to Our Product Development, Regulatory Approval and Commercialization*" for more information regarding the risks associated with clinical development.

Selling, General and Administrative Expenses

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

Due to the general growth of the organization associated with administering ongoing and planned clinical trials and our focus on commercial preparedness, we expect that our selling, general and administrative expenses may

increase. We will incur increased accounting, audit, legal, regulatory, compliance, director and officer insurance costs as well as investor and public relations expenses associated with being a public company. Additionally, if and when a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and expenses as a result of our preparation for commercial operations.

Interest Income

Interest income is recognized using the effective interest rate method. Finance income for the three and nine months ended September 30, 2024 and 2023 is related to interest earned on cash balances.

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. Our foreign currency exposure is mainly related to the Euro. As of September 30, 2024, our net exposure to foreign currency risk was $110.5 million, as compared to $114.3 million as of December 31, 2023.

Income Tax

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

Results of Operations

Comparison of the three months ended September 30, 2024 and 2023

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

	For the three months ended September 30,		
(In thousands of USD)	**2024**	**2023**	**Change**
Revenue	29,111	2,941	26,170
Operating Expenses:			
Research and development expenses	35,702	43,371	(7,669)
Selling, general and administrative expenses	18,412	9,128	9,284
Total operating expenses	54,114	52,499	1,615
Operating Loss	(25,003)	(49,558)	24,555
Other income (expense):			
Interest Income	4,443	3,059	1,384
Fair value change - earnout and warrants	(770)	2,521	(3,291)
Foreign exchange gains/(losses)	4,682	(3,155)	7,837
Loss before tax	(16,648)	(47,133)	30,485
Income tax expense	(1)	—	(1)
Loss for the period	(16,647)	(47,133)	30,486

Revenue

Revenue was $29.1 million for the three months ended September 30, 2024 compared to $2.9 million for the three months ended September 30, 2023, an increase of $26.2 million or 890%. This increase was largely due to a clinical success milestone of $27.3 million pursuant to the Menarini License, which was earned in the three months ended September 30, 2024 while there were no clinical success milestones earned during the three months ended September 30, 2023. The amount of deferred revenue that was recognized during the three months ended September 30, 2024 was $1.1 million less than the amount of deferred revenue recognized during the three months ended September 30, 2023, which accounts for the remainder of the change.

Research and Development Expenses

Research and development expenses were $35.7 million for the three months ended September 30, 2024 compared to $43.4 million for the three months ended September 30, 2023, a decrease of $7.7 million, or 18%. This was primarily driven by:

•a $6.6 million decrease in clinical expenses related to clinical trials which are completed or nearing completion;

•a $1.9 million decrease in manufacturing costs; and

•a partially offsetting $0.8 million increase in personnel costs.

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

	For the three months ended September 30,		
(In thousands of USD)	**2024**	**2023**	**Change**
Clinical expenses	24,083	30,638	(6,555)
Non-clinical expenses	707	1,168	(461)
Personnel expenses	5,448	4,666	782
Manufacturing costs	4,612	6,554	(1,942)
Regulatory expenses	819	301	518
Other research and development costs	33	44	(11)
Total research and development expenses	**35,702**	**43,371**	**(7,669)**

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $18.4 million for the three months ended September 30, 2024 compared to $9.1 million for the three months ended September 30, 2023, an increase of $9.3 million, or 102%. This was primarily driven by:

•a $6.5 million increase in personnel costs related to selling, general and administrative expenses primarily driven by our share-based compensation arrangements which account for $2.8 million of the increase. The remainder is largely due to increased recruitment and employment costs for individuals involved with administrative and commercial preparedness activities to support the growth of the organization; and

•a $2.4 million increase in marketing and communication expenses related to startup costs as we begin to build capabilities to support our planned commercial launch of obicetrapib, if approved.

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

	For the three months ended September 30,		
(In thousands of USD)	**2024**	**2023**	**Change**
Personnel expense	10,729	4,263	6,466
Intellectual property	640	500	140
Legal costs	639	769	(130)
Finance and administration	1,135	1,275	(140)
Marketing and communication	3,546	1,142	2,404
Commission expense	49	121	(72)
Facility-related and other costs	1,674	1,058	616
Total selling, general and administrative expenses	**18,412**	**9,128**	**9,284**

Interest Income

Interest income was $4.4 million for the three months ended September 30, 2024 compared to $3.1 million for the three months ended September 30, 2023, an increase of $1.3 million, or 45%. This increase was driven by interest earned on cash balances.

Fair Value Change - Earnout and Warrants

Fair value change - earnout and warrants was a loss of $0.8 million for the three months ended September 30, 2024 compared to a gain of $2.5 million for the three months ended September 30, 2023. The change is driven by changes in the market prices during the period for our Ordinary Shares and Warrants which trade under the symbols "NAMS" and "NAMSW," respectively, and an increase from 40% to 65% in the estimated probability of completing the milestone related to the earnout which is an input to the fair value of the derivative earnout liability.

Foreign Exchange Gains/(Losses)

Net foreign exchange gains/(losses) were a gain of $4.7 million for the three months ended September 30, 2024 compared to a loss of $3.2 million for the three months ended September 30, 2023. This change was largely driven by movements in the exchange rate for Euros, which is our primary foreign currency exposure.

Loss for the Period

Loss for the period was $16.6 million for the three months ended September 30, 2024 compared to $47.1 million for the three months ended September 30, 2023, a decrease of $30.5 million. The individual components of the change are described above.

Comparison of the nine months ended September 30, 2024 and 2023

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

	For the nine months ended September 30,		
(In thousands of USD)	**2024**	**2023**	**Change**
Revenue	32,791	13,287	19,504
Operating Expenses:			
Research and development expenses	116,511	118,132	(1,621)
Selling, general and administrative expenses	49,340	27,048	22,292
Total operating expenses	165,851	145,180	20,671
Operating Loss	(133,060)	(131,893)	(1,167)
Other income (expense):			
Interest Income	12,396	8,615	3,781
Fair value change - earnout and warrants	(30,028)	(4,004)	(26,024)
Foreign exchange gains/(losses)	1,270	(160)	1,430
Loss before tax	(149,422)	(127,442)	(21,980)
Income tax expense	(1)	—	(1)
Loss for the period	(149,421)	(127,442)	(21,979)

Revenue

Revenue was $32.8 million for the nine months ended September 30, 2024 compared to $13.3 million for the nine months ended September 30, 2023, an increase of $19.5 million, or 147%. This increase was largely due to the recognition of $27.3 million of revenue from the Menarini License related to a clinical development milestone achieved in the nine months ended September 30, 2024, compared to $5.4 million of revenue related to clinical development milestones recognized in the nine months ended September 30, 2023. The increase in revenue related to clinical development milestones pursuant to the Menarini License was partially offset by a decrease in the amount of previously deferred revenue recognized from the Menarini License related to the research and development performance obligation. The amount of such revenue recognized was $5.5 million in the nine months ended September 30, 2024 as compared to $7.9 million recognized in the nine months ended September 30, 2023.

Research and Development Expenses

Research and development expenses were $116.5 million for the nine months ended September 30, 2024 compared to $118.1 million for the nine months ended September 30, 2023, a decrease of $1.6 million, or 1%. This change is made up of:

- a $7.7 million decrease in manufacturing costs;
- a $1.7 million decrease in non-clinical expenses related to pre-clinical studies;
- a partially offsetting $1.1 million increase in personnel expenses; and
- a partially offsetting $5.6 million increase in clinical expenses driven by costs incurred in the first half of 2024 as the Company enrolled and executed its clinical trial program, slightly offset by an reduction of costs in the three months ended September 30, 2024 as certain clinical trials are completed or nearing completion.

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

(In thousands of USD)	For the nine months ended September 30, 2024	2023	Change
Clinical expenses	84,174	78,601	5,573
Non-clinical expenses	1,503	3,166	(1,663)
Personnel expenses	16,366	15,252	1,114
Manufacturing costs	12,550	20,296	(7,746)
Regulatory expenses	1,719	725	994
Other research and development costs	199	92	107
Total research and development expenses	**116,511**	**118,132**	**(1,621)**

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $49.3 million for the nine months ended September 30, 2024 compared to $27.0 million for the nine months ended September 30, 2023, an increase of $22.3 million, or 82%. This change is made up of:

- a $15.3 million increase in personnel expenses related to selling, general and administrative expenses of which our share-based compensation arrangements account for $7.6 million. The remainder is largely due to increased recruitment and employment costs for individuals involved with administrative and commercial preparedness activities to support the growth of the organization;
- an $8.9 million increase in marketing and communication expenses related to startup costs as we begin to build capabilities to support our planned commercial launch of obicetrapib, if approved;
- a $1.2 million increase in facility-related and other costs; and
- a partially offsetting $2.8 million decrease in finance and administration expenses which is primarily due to costs incurred in 2023 in connection with an underwritten public offering of Ordinary Shares by certain of our shareholders. We did not sell any Ordinary Shares in the offering and did not receive any proceeds from the offering.

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

(In thousands of USD)	For the nine months ended September 30, 2024	2023	Change
Personnel expense	27,693	12,441	15,252
Intellectual property	1,591	1,284	307
Legal costs	1,530	1,992	(462)
Finance and administration	3,205	5,983	(2,778)
Marketing and communication	11,143	2,229	8,914
Commission expense	150	252	(102)
Facility-related and other costs	4,028	2,867	1,161
Total selling, general and administrative expenses	**49,340**	**27,048**	**22,292**

Interest Income

Interest income was $12.4 million for the nine months ended September 30, 2024 compared to $8.6 million for the nine months ended September 30, 2023, an increase of $3.8 million, or 44%. This increase was driven by interest earned on cash balances.

Fair Value Change - Earnout and Warrants

Fair value change - earnout and warrants was a loss of $30.0 million for the nine months ended September 30, 2024 compared to a loss of $4.0 million for the nine months ended September 30, 2023. The change is driven by changes in the market price during the period for our Ordinary Shares and Warrants which trade under the symbols

"NAMS" and "NAMSW," respectively, and an increase from 40% to 65% in the estimated probability of completing the milestone related to the earnout which is an input to the fair value of the derivative earnout liability.

Foreign Exchange Gains/(Losses)

Net foreign exchange gains/(losses) were a gain of $1.3 million for the nine months ended September 30, 2024 compared to a loss of $0.2 million for the three months ended September 30, 2023. This change was largely driven by movements in the exchange rate for Euros, which is our primary foreign currency exposure.

Loss for the Period

Loss for the period was $149.4 million for the nine months ended September 30, 2024 compared to $127.4 million for the nine months ended September 30, 2023, an increase of $22.0 million. The individual components of the change are described above.

Liquidity and Capital Resources

Overview

To date, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, undertaking preclinical studies and conducting clinical trials of obicetrapib. As a result, we are not yet profitable and have incurred losses in each annual period since our inception. As of September 30, 2024, we had an accumulated loss of $466.4 million. We expect to continue to incur significant losses for the foreseeable future.

We have historically funded our operations primarily through private and public placements of shares, the sale of convertible notes, proceeds from the Menarini License and the proceeds from the closing of the transactions contemplated by the Business Combination Agreement, dated July 25, 2022 (the "Business Combination Agreement"), by and among the Company, NewAmsterdam Pharma Holding B.V., Frazier Lifesciences Acquisition Corporation ("FLAC"), and NewAmsterdam Pharma Investment Corporation (the "Business Combination"). As of September 30, 2024, we had cash of $422.7 million.

Sources of Liquidity

Follow-on Offering

On February 16, 2024, we completed the Offering of 5,871,909 Ordinary Shares at a public offering price of $19.00 per Ordinary Share and, in lieu of Ordinary Shares to certain investors, Pre-Funded Warrants to purchase 4,736,841 Ordinary Shares at a public offering price of $18.9999 per Pre-Funded Warrant, which represents the per share public offering price for the Ordinary Shares less the $0.0001 per share exercise price for each such Pre-Funded Warrant. Of the 5,871,909 Ordinary Shares issued and sold in the Offering, 1,383,750 Ordinary Shares were issued and sold pursuant to the exercise of the underwriters' option to purchase additional Ordinary Shares at the public offering price per share. The Ordinary Shares and Pre-Funded Warrants were issued and sold pursuant to an underwriting agreement among the Company and Jefferies LLC, Leerink Partners LLC, Piper Sandler & Co. and RBC Capital Markets, LLC, as representatives of the several underwriters listed on Schedule A thereto. The net proceeds to the Company from the Offering were $190.0 million after deducting underwriting discounts and commissions and offering expenses payable by the Company.

At-the-Market Offering

On August 9, 2024, we entered into an Amended and Restated Sales Agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen") and TD Securities (USA) LLC ("TD Cowen"), an affiliate of Cowen, pursuant to which we may issue and sell from time to time up to $150 million of our Ordinary Shares through or to TD Cowen as our sales agent or acting as principal in any method deemed to be an "at the market offering." The Sales Agreement amends and restates the sales agreement, dated December 7, 2023, between us and Cowen (the "Prior Sales Agreement"). TD Cowen will receive a commission of up to 3.0% of the gross proceeds of any Ordinary Shares sold pursuant to the Sales Agreement. During the nine months ended September 30, 2024, we did not sell any Ordinary Shares pursuant to the Sales Agreement or the Prior Sales 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 €868 million upon the achievement of various clinical, regulatory and commercial milestones, €30 million of which has been received to date. If obicetrapib is approved, and successfully commercialized by Menarini, we will be entitled to tiered royalties ranging from the low double-digits to the mid-twenties as a percentage of net sales in the Menarini Territory, with royalty step-downs in the event of generic entrance or in respect of required third-party intellectual property payments. See the section titled "*Business—Commercial*" contained in our Annual Report for a full description of the Menarini License.

As of September 30, 2024, we have received a total of €30 million in milestone payments from Menarini, €25 million of which was received in the nine months ended September 30, 2024.

Warrants

In the nine months ended September 30, 2024, 1,317,069 Warrants were exercised at an exercise price of $11.50 per Ordinary Share generating gross proceeds of $13.4 million. As of September 30, 2024, we had another 2,700,152 outstanding Warrants to purchase 2,700,152 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 $31.1 million assuming the exercise of all Warrants outstanding as of September 30, 2024. The exercise of the Warrants, and any proceeds we may receive from their exercise, are highly dependent on the price of our Ordinary Shares and the spread between the exercise price of the Warrant and the price of an Ordinary Share at the time of exercise. For example, to the extent that the trading price of the Ordinary Shares exceeds $11.50 per share, it is more likely that holders of our Warrants will exercise their Warrants. If the trading price of the Ordinary Shares is less than $11.50 per share, it is unlikely that such holders will exercise their Warrants. The exercise price of the Warrants has at times exceeded the market price of the Ordinary Shares. To the extent that the price of our Ordinary Shares is below $11.50, we believe that the Warrant holders will be unlikely to cash exercise their warrants, resulting in little to no cash proceeds to us. There can be no assurance that our Warrants will be in the money prior to their expiration and, as such, certain unexercised Warrants may expire worthless. As such, it is possible that we may never generate any additional cash proceeds from the exercise of our Warrants. We have not included, and do not intend to include, any potential cash proceeds from the exercise of our Warrants in our short-term or long-term liquidity projections. We will continue to evaluate the probability that the Warrants are exercised over the life of our Warrants and the merit of including potential cash proceeds from the exercise thereof in our liquidity projections.

Cash Flows

The following is a summary of cash flows for the nine months ended September 30, 2024 and 2023:

	For the nine months ended September 30,	
(In thousands of USD)	**2024**	**2023**
Net cash (used in)/provided by operating activities	(121,083)	(108,144)
Net cash used in investing activities	(669)	(21)
Net cash provided by financing activities	202,896	8,912
Foreign exchange differences	1,135	(168)
Cash at the beginning of the period	340,450	467,728
Cash at the end of the period	**422,729**	**368,307**

Net Cash Flows Used In Operating Activities

Net cash flows used in operating activities was $121.1 million in the nine months ended September 30, 2024 compared to $108.1 million in the nine months ended September 30, 2023, an increase of $13.0 million. This change was primarily due to an increase in research and development and selling, general and administrative expenditures, the underlying reasons for which are described above, partially offset by an increase in revenue earned related to clinical development milestones in the current period as compared to the same period in the prior year.

Net Cash Flows Used In Investing Activities

Net cash flows used in investing activities was $0.7 million in the nine months ended September 30, 2024 compared to $0.0 million in the nine months ended September 30, 2023, an increase of $0.7 million. This change was primarily due to investments in internal use software and computer equipment to support our growing organization.

Net Cash Flows Provided By Financing Activities

Net cash flows provided by financing activities was $202.9 million in the nine months ended September 30, 2024 compared to $8.9 million in the nine months ended September 30, 2023, an increase of $194.0 million. This change was primarily related to the Offering, which generated net proceeds of $190.0 million after deducting underwriting discounts and commissions and offering expenses payable by the Company. The remaining change is due to a $4.8 million increase in the proceeds received from the exercise of Warrants, partially offset by a $0.5 million net outflow upon the exercise of options after taking into account the payment of related withholding taxes.

Operating Capital and Capital Expenditure Requirements

Third-Party Service Agreements

We have entered into a variety of agreements and financial commitments in the normal course of business with CROs, CMOs, and other third parties for preclinical and clinical development and manufacturing services. The terms generally provide us with the option to cancel, reschedule and adjust our requirements based on our business needs, prior to the delivery of goods or performance of services. Payments due upon cancellation generally consist only of payments for services provided or expenses incurred, including non-cancelable obligations of our service providers, up to the date of cancellation. However, some of our service providers also charge cancellation fees upon cancellation. The amount and timing of such payments are not known, but at September 30, 2024 they are estimated to be a maximum of $14.0 million due within one year and $2.7 million due in more than a year. As at September 30, 2024, we had cash of $422.7 million, which is sufficient to fund these obligations.

Leases

We are party to a services agreement (the "Naarden Lease") pursuant to which an affiliate of Forbion leased us office space, the office lease agreement with Renaissance Aventura LLC, dated May 24, 2021, as amended April 9, 2024 (as amended, the “Miami Lease”) and an office sublease agreement with GR8 People, Inc., dated April 2, 2024 (the “Yardley Lease”). Under the Naarden Lease, we are obligated to pay €40 thousand per year in rent. The Naarden Lease will continue until terminated by either us or the landlord. Pursuant to the Miami Lease, we are required to pay annual rent ranging from $75 thousand to $82 thousand, increasing from the low end of the range to the higher end of the range for each year of the lease. The Miami Lease will expire by its terms on October 31, 2027, unless terminated earlier by either party pursuant to the terms of the Miami Lease. Pursuant to the Yardley Lease, we are required to pay annual rent ranging from $189 thousand to $194 thousand, increasing from the low end of the range to the higher end of the range for each year of the lease. The Yardley Lease will expire by its terms on April 3, 2026, unless terminated earlier by either party pursuant to the terms of the Yardley Lease.

Menarini License

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

Critical Accounting Policies and Estimates

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

See Note 2 to our consolidated financial statements in the Annual Report for a summary of significant accounting policies and the effect on our consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

We are exposed to market risk, credit risk and liquidity risk. Our senior management oversees the management of these risks. The Company's Board of Directors (the "Board of Directors") reviews and approves policies for managing each of these risks, which are summarized below.

Market Risk

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

Interest Rate Risk

We are exposed to interest rate risk primarily through our cash. Changes in interest rates may cause variations in interest income and expense resulting from short-term interest-bearing assets. Given our only interest-bearing financial instrument is cash we do not believe an immediate 100 basis point change in interest rates would have a material effect on our financial condition.

Foreign Currency Risk

Foreign currency risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in foreign exchange rates. Our exposure to the risk of changes in foreign exchange rates relates primarily to cash and trade and other payables denominated in currencies other than our functional currency, the U.S. Dollar. As of September 30, 2024, our net exposure to foreign currency risk was $110.5 million, mainly related to the Euro. As of September 30, 2024, the effect of a hypothetical 1% change in exchange rates on currencies denominated in other than our functional currency would result in a potential change in future earnings in our consolidated statement of operations of approximately $1.1 million.

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

Other Market Price Risk

As a result of the Business Combination, we have derivative warrant liabilities and a derivative earnout liability which are measured at fair value through profit or loss. As at September 30, 2024, the fair value of the derivative warrant liabilities and the derivative earnout liability were $18.9 million and $18.8 million, respectively. The value of the derivative warrant liability is directly correlated to the market price of a publicly traded Warrant, which is traded under the symbol NAMSW. With all other variables held constant, a 1% change in the market price

of NAMSW would change the value of the derivative warrant liability by 1%, or $0.2 million. The value of the derivative earnout liability is directly correlated to the market price of a publicly traded Ordinary Share, which is traded under the symbol NAMS. With all other variables held constant, a 1% change in the market price of NAMS would change the value of the derivative earnout liability by 1%, or $0.2 million.

Credit Risk

Credit risk is the risk that a counterparty will not meet its obligations under a financial instrument or customer contract, leading to a financial loss. We are exposed to credit risk primarily from our treasury activities, including deposits with banks and financial institutions and have limited credit risk exposure from our operating activities. We hold available cash in bank accounts with banks which have investment grade credit ratings. Management periodically reviews the creditworthiness of the banks with which it holds assets.

We perform research and development activities and do not yet have any sales. We are able to reclaim value added tax, 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 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of the Chief Executive Officer (who is our principal executive officer) and Chief Financial Officer (who is our principal financial officer), evaluated the effectiveness of our disclosure controls and procedures, as defined in Rule 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of September 30, 2024. The term "disclosure controls and procedures" means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that as of September 30, 2024, our disclosure controls and procedures were not effective due to the un-remediated material weaknesses in internal control, previously disclosed in the Annual Report and include the following:

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

Notwithstanding the material weaknesses, management has concluded that our financial statements included in this Quarterly Report are fairly stated in all material respects in accordance with U.S. GAAP for each of the periods presented herein.

Remediation

The Company's management, under the oversight of the Audit Committee, is committed to further strengthen and maintain a strong internal control environment and has continued in 2024 the process of executing its remediation plan which included the following measures:

- performed a detailed risk assessment;

•hired additional internal and external accounting resources, including third-party internal control advisors and technical accounting advisors;

•redesigned and documented critical processes and controls associated with internal control over financial reporting;

•designed and maintained formal accounting policies;

•designed and implemented procedures and controls over the fair presentation of our financial statements;

•implemented a new ERP system;

•established segregation of duties and management review and approvals across all key business processes, applications and controls over information technology;

•designed and implemented controls over the preparation and review of journal entries and financial statements;

•designed and implemented controls over financial reporting and information technology; and

•implemented management audit tooling to follow up on control performance.

Although the above listed measures were implemented during 2023 and performance continued in the first half of 2024, management is still in the process of testing the implemented controls and refining the remediation plan based on the results. Therefore management does not consider the identified material weaknesses to be fully remediated yet. Management is committed to further strengthen its internal control environment in fiscal year 2024.

Changes in Internal Controls over Financial Reporting

Other than the ongoing remediation efforts described above, there were no changes in our internal control over financial reporting (as defined in Rules 13a15(f) and 15d-15(f) under the Exchange Act), during the three months ended September 30, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls and Procedures

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not party to any material pending legal proceedings. From time to time, we may be involved in legal proceedings arising in the ordinary course of business.

Item 1A. Risk Factors

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

Those risk factors below denoted with a "" are newly added or have been materially updated from our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 28, 2024.*

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

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

We are a clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. Pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of uncertainty. Our operations to date have been limited to developing and undertaking clinical trials of our product candidate, obicetrapib. We are not profitable and have not generated product revenue from operations. We have historically incurred net losses since we commenced operations in October 2019. For the year-to-date period ended September 30, 2024, we incurred a net loss of $149.4 million and as of September 30, 2024, we had an accumulated deficit of $466.4 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future, considering the current research and development stage of our activities, as we do not have products approved for commercial sale. Our ability to ultimately achieve recurring product revenues and profitability is dependent upon our ability to successfully complete the development of obicetrapib and obtain necessary regulatory approvals for, and successfully manufacture, market and commercialize, our product together with our partners.

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

Our future capital requirements depend on many factors, including:

- the timing of, and the costs involved in, clinical development and obtaining regulatory approvals for our product candidate;
- changes in regulatory requirements during the development phase that can delay or force us to stop our activities related to obicetrapib or any of our future product candidates;
- the cost of commercialization activities if obicetrapib is approved for sale, including marketing, sales and distribution costs;
- the cost of third-party manufacturing of our product candidate;
- the number and characteristics of any other product candidates we develop or acquire;

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

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

•the expenses needed to attract and retain skilled personnel;

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

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

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

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

•scientific breakthroughs in the field of treatment for 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. As of September 30, 2024, we had cash of $422.7 million.

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

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

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

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

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

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

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

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

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

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

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

We currently maintain substantially all of our funds in cash deposit accounts at three financial institutions. The amounts held in our deposit accounts are, and in the future, may be, in excess of the insurance limit of $250,000 and €100,000 provided by the FDIC and Dutch Deposit Guarantee Scheme, respectively. In the event of a failure of any of these financial institutions where we maintain our deposits or other assets, we may incur a loss to the extent such loss exceeds such limitations, which could have a material adverse effect upon our liquidity, financial condition and our results of operations.

Risks Related to Our Product Development, Regulatory Approval and Commercialization

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

We have invested almost all of our efforts and financial resources in the research and development of obicetrapib. Our future success, including our ability to generate revenue, depends on our ability to develop, commercialize, market and sell obicetrapib. However, obicetrapib has yet to receive marketing approval from the FDA, the EMA or other comparable regulatory authorities. We currently generate no revenue from the sale of any products, and we may never be able to develop or commercialize a marketable product.

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

- our ability to successfully complete our clinical trials, including timely patient enrollment and acceptable safety and efficacy data and our ability to demonstrate the safety and efficacy of obicetrapib;
- unless we have received a deferral or waiver, our ability to complete successfully any pediatric clinical trials agreed pursuant to the Pediatric Research Equity Act or its 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 ("AEs") associated with obicetrapib;
- whether we are required by the FDA, the EMA or other comparable regulatory authorities to conduct additional preclinical studies or clinical trials, and the scope and nature of such studies or trials, prior to approval to market our product, such as a cardiovascular outcomes trial;
- the timely receipt of necessary marketing approvals from the FDA, the EMA and other comparable regulatory authorities, including pricing and reimbursement determinations;
- the ability to successfully commercialize obicetrapib, if approved, for marketing and sale by the FDA, the EMA or other comparable regulatory authorities;
- our ability and the ability of our third party manufacturing partners to timely and satisfactorily manufacture quantities of obicetrapib at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability;
- our success in educating healthcare providers and patients about the benefits, risks, administration and use of obicetrapib, if approved;
- acceptance of obicetrapib, if approved, as safe and effective by patients and the healthcare community;
- the maintenance of an acceptable safety profile of our product following any approval;
- the availability, perceived advantages, relative cost, safety and efficacy of alternative and competing treatments for the indications addressed by obicetrapib;

•entering into, on favorable terms, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize obicetrapib;

•the effectiveness of our and any current or future collaborators' marketing, sales and distribution strategy, and operations;

•our ability to obtain, protect and enforce our intellectual property rights with respect to obicetrapib; and

•our ability to implement strategies to minimize the impact of pandemics or other health epidemics to our business, including with respect to initiating, enrolling, conducting or completing our planned and ongoing clinical trials of obicetrapib and addressing any potential disruption or delays to the supply of our product candidates.

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

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

As a company, we have never progressed a product candidate through to regulatory approval. We have not previously submitted an NDA, an EU marketing authorization application ("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. Results of earlier studies and trials may not be predictive of future trial results and our clinical trials may fail to adequately demonstrate the safety and efficacy of obicetrapib.

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

•obtain allowance from the FDA or comparable foreign regulatory authorities in order to commence a trial;

•identify, recruit and train suitable clinical investigators;

•reach agreement on acceptable terms with prospective contract research organizations ("CROs"), and clinical trial sites, and have such CROs and sites effect the proper and timely conduct of our clinical trials;

•obtain and maintain investigational review board ("IRB") or independent 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, including large CVOTs, 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.

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

We depend on enrollment 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 our ongoing or future clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented. The enrollment of subjects depends on many additional factors, including:

•the subject eligibility criteria defined in the protocol;

•the general willingness of subjects to enroll in the trial;

•patient compliance with the trial protocols;

•the sample size of the subjects required for analysis of the trial's primary endpoints;

•the proximity of subjects to trial sites;

•the design of the trial;

•our ability to recruit clinical trial investigators with the appropriate competencies and experience;

•clinicians' and subjects' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new therapies that may be approved for the indications we are investigating;

•the clinical site's ability to obtain and maintain subject consents; and

•clinical trial participants may not comply with clinical trial protocol procedures and instructions.

Our clinical trials may also compete with other clinical trials for product candidates that seek to treat 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.

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 have disclosed and may in the future publicly disclose preliminary or "topline" data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or clinical trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the "topline" or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. "Topline" data also remain subject to audit and verification procedures that may result in the final data being materially different from the data we previously published. As a result, "topline" data should be viewed with caution until the final data are available.

Additionally, we have disclosed and may in the future 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 or that additional data must be included;

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

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

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

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

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

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

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

Our ongoing clinical trials 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 CVOT, in patients with ASCVD. The completion of these clinical trials or any of our other ongoing or future clinical trials may be delayed for a number of reasons, including:

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

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

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

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

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

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

•reports from preclinical or clinical testing of other 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. Significant nonclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may materially harm our business and results of operations.

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

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

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

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

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

- our inability to file an NDA or similar application for obicetrapib because of insufficient benefit-risk profile, or the denial of such application by the FDA, the EMA or other comparable regulatory authorities;
- the FDA, the EMA or other comparable regulatory authorities suspending or withdrawing their approval of the product;
- the FDA, the EMA or other comparable regulatory authorities requiring the addition of labeling statements, such as warnings or contraindications or distribution and use restrictions;
- the FDA, the EMA or other comparable regulatory authorities requiring us to issue specific communications to healthcare professionals, such as letters alerting them to new safety information about our product, changes in dosage or other important information;
- the FDA, the EMA or other comparable regulatory authorities issuing negative publicity regarding the affected product, including safety communications;

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

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

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

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

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

Our ongoing clinical trials are being conducted both within and outside the United States, and we intend to conduct portions of our future clinical trials outside the United States. The acceptance of clinical trial data by the FDA, EMA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions, or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to 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 future global health crises could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

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

Separately, in response to the COVID-19 pandemic, the FDA temporarily postponed routine surveillance inspections of manufacturing facilities. Subsequently, the FDA resumed standard inspectional operations of domestic facilities. If a prolonged government shutdown occurs, or if global health crises prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

Any regulatory approvals that we receive for obicetrapib or future product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, risk mitigation and surveillance to monitor the safety and efficacy of the product candidate, and we may be required to include labeling that includes significant use or distribution restrictions or significant safety warnings, including

boxed warnings. Such requirements could negatively impact us by reducing revenues or increasing expenses, and cause the approved product not to be commercially viable. Absence of long-term safety data may further limit the approved uses of our product, if any.

If the FDA, the EMA or other comparable regulatory authority approves obicetrapib, the manufacturing processes, labeling, packaging, distribution, AE reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration requirements and continued compliance with 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 AEs of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

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

The FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. Comparable restrictions apply in the EU, where, in addition, the advertising of prescription only medications to the general public is prohibited.

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 as both a monotherapy and in combination with one or more approved therapies. For example, we are evaluating obicetrapib in combination with ezetimibe, including the combination on top of high intensity statin therapy. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, the EMA, the MHRA, the PMDA, the NMPA or other comparable regulatory authorities could revoke approval of the therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing therapies. If the therapies we use in combination with our product candidate are replaced as the standard of care for the indications we choose for any of our product candidate, the FDA, the EMA, the MHRA, the PMDA, the NMPA or other comparable regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own product, if approved, being removed from the market or being less successful commercially.

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

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

If we are not successful in our efforts to discover 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 or other 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, lack of efficacy, 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 or utilize a variety of types of collaboration, license, monetization, distribution and other arrangements with other third parties relating to the development or commercialization, once approved, of obicetrapib or future product candidates or indications. We may also become reliant on the research efforts of third parties for any such product candidates that we do not intend to conduct preclinical studies or early-stage clinical trials for. If we do not successfully develop and begin to commercialize product candidates, we will face difficulty in obtaining product revenues in future periods, which could result in significant harm to our financial position and potential for growth and adversely affect the price of the Ordinary Shares.

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

Because we have limited financial and management resources, we are currently primarily focused on the development of obicetrapib for 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 PSCK9 inhibitor injectables from Amgen Inc., Regeneron Pharmaceuticals, Inc. and Novartis International AG. We may also face competition from oral therapeutics containing bempedoic acid from Esperion. We are aware that Merck has decided to advance its oral PSCK9 inhibitor, MK-0616, into Phase 3 development. 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 for all aspects of the manufacturing of obicetrapib for clinical trials, and expect to continue to do so to support commercial scale production of obicetrapib, if approved. There are significant risks associated with contracting with third-party suppliers, including their ability to meet the increased need that may result from our potential commercialization efforts. This increases the risk that we will not have sufficient quantities of obicetrapib or be able to obtain such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We currently rely on third-party contract manufacturing organizations ("CMOs") and suppliers for all of our required raw materials, active ingredients and finished products for our clinical trials. Because there are a limited number of suppliers for the raw materials that we use to manufacture our product candidate, we may need to engage alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidate for our clinical trials, and if approved, ultimately for commercial sale. We do not have any control over the availability of raw materials. If we or our manufacturers are unable to purchase these raw materials on acceptable terms, at sufficient quality levels or in adequate quantities, if at all, the development and commercialization of our product candidate or any future product candidates would be delayed, or there would be a shortage in supply, which would impair our ability to meet our development objectives for our product candidates or generate revenues from the sale of any approved products. We currently rely on several CMOs to produce both drug substances and drug products required for our clinical trials. While we believe our existing suppliers are sufficient and that alternative sources of supply exist if needed, there can be no assurance that we will be able to quickly establish additional or replacement

sources if needed, and a reduction or interruption in supply could adversely affect our ability to manufacture our product candidate in a timely or cost-effective manner.

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

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

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

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

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

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

- the inability to meet our product candidate specifications, including product formulation, and quality requirements consistently;
- a delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues, including those related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- a failure to comply with cGMP and similar quality standards;
- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- the reliance on a limited number of sources, and in some cases, single sources for key materials, such that if we are unable to secure a sufficient supply of these key materials, we will be unable to manufacture and sell obicetrapib in a timely fashion, in sufficient quantities or under acceptable terms;
- the lack of qualified backup suppliers for those materials that are currently or in the future purchased from a sole or single source supplier;

•operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier;

•resource constraints, including as a result of labor disputes or unstable political environments;

•carrier disruptions or increased costs that are beyond our control; and

•the failure to deliver our products under specified storage conditions and in a timely manner.

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

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

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

We and the third parties upon whom we rely are required to comply with GCP, which are regulations and guidelines enforced by regulatory authorities around the world for products in clinical development. Regulatory authorities enforce these GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or our third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and our submission of marketing applications may be delayed or the regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, a regulatory authority will determine that any of our clinical trials comply or complied with applicable GCP regulations. In addition, our clinical trials must be conducted with material produced under current cGMP regulations, which are enforced by regulatory authorities. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be impacted if our CROs, clinical investigators or other third parties violate federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

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

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

While we currently plan to commercialize our own products, if approved, in the United States, we entered into the Menarini License to obtain and maintain regulatory approvals, commercialize and undertake local development, in each case with respect to obicetrapib either as a sole active ingredient product or in a fixed dose combination with ezetimibe for any use, in certain areas of Europe. Our collaboration with Menarini is critical in these areas, as we do not currently have the internal capacity to market, sell and distribute obicetrapib, if approved, in Europe. Pursuant to the Menarini License, Menarini is responsible for 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.

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

If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and distribution capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization costs. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. In addition, we may not be able to

hire a sales force in the United States that is sufficient in size or has adequate expertise to target the areas that we intend to target. If we are unable to establish a sales force and marketing and distribution capabilities, our operating results may be adversely affected.

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

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

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

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

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

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

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

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

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

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

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

•collaborators may not perform their obligations as expected;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Specifically, research, sales, marketing, education and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, education, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics and train our employees on these topics, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, even if we are successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and reputation. Violations of such laws subject us to numerous penalties, including, but not limited to, the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts, business operations and environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste

products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance.

Risks Related to Our Business and Strategy

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

As of September 30, 2024, we had 62 employees and 13 consultants. We expect to continue to expand our development, quality, sales, managerial, operational, finance, marketing and other resources in order to manage our operations and clinical trials, continue our development activities and commercialize obicetrapib, if approved. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our expansion strategy requires that we:

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

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

If obicetrapib or our future product candidates receive approval for marketing, and 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 the FDA, the EMA or other comparable regulatory authorities as reflected in the product's approved labeling. For example, if we receive marketing approval for obicetrapib for cardiometabolic disease, physicians, in their professional medical judgment, may nevertheless prescribe obicetrapib to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label use, we may become subject to significant liability under the Federal Food, Drug, and Cosmetic Act (the "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 candidate. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

•fluctuations in foreign currency exchange rates;

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

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

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

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

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

•difficulties in attracting and retaining qualified personnel;

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

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

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

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

Negative economic conditions, including as a result of commodity price inflation or supply chain constraints, widespread health crises, the war in Ukraine and Israel, may adversely impact our results of operations.

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

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

The estimates and assumptions included in this Quarterly Report and the exhibits attached, 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 and the timing of obtaining such approvals, if ever. These estimates and assumptions are subject to various factors beyond our control, including, for example, changes in the supply of drug products required for our clinical trials, increased costs for such drugs, changes in the regulatory or competitive environment, delays in our clinical trials or in obtaining regulatory approvals, lower than expected rates of reimbursement on our product candidate, if approved, the imposition or heightening of sanctions or other economic or military measures in relation to the wars in Ukraine and Israel, and changes in our executive team. Accordingly, our future financial condition and results of operations may differ materially from our estimates.

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

We may acquire companies, businesses and products, or in-license additional product candidates, that complement or augment our existing business. Any product candidate or technologies we in-license or acquire will likely require additional development efforts prior to commercial sale, including extensive preclinical or clinical testing, or both, and approval by the FDA, the EMA and other comparable regulatory authorities, if any. All product candidates are prone to risks of failure inherent in pharmaceutical product development, including the possibility that the product candidate, or product developed based on in-licensed technology, will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we may not be able to integrate any acquired business successfully or operate any acquired business profitably. Integrating any newly acquired business or product could be expensive and time-consuming. Integration efforts often take a significant amount of time, place a significant strain on managerial, operational and financial resources, result in loss of key personnel and could prove to be more difficult or expensive than we predict. The diversion of our management's attention and any delay or difficulties encountered in connection with any future acquisitions or in-licenses that we may consummate could result in the disruption of our

on-going business or inconsistencies in standards and controls that could negatively affect our ability to maintain third-party relationships. Moreover, we may need to raise additional funds through public or private debt or equity financing, or issue additional shares, to acquire any businesses or products, which may result in dilution for shareholders or the incurrence of indebtedness.

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

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

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

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

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

Successful and attempted attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. We may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

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

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

Risks Related to Our Intellectual Property

We may not be successful in obtaining all of the necessary intellectual property rights to allow us to develop and commercialize our product candidate, obicetrapib. If our efforts to obtain, protect or enforce our patents and other intellectual property rights related to our product candidates and technologies are not adequate, including due to the risk that we are unaware of prior art that may affect the validity of our patents, we may not be able to compete effectively in our market and we otherwise may be harmed.

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

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

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

The patent applications that we own or license may fail to result in issued patents in the United States or granted patents in foreign jurisdictions. Our ability to obtain and maintain valid and enforceable patents depends on various factors, including determination that our patent claims are patentable over prior art. We may be subject to a third-party preissuance submission of prior art to the United States Patent and Trademark Office (the "USPTO") or foreign patent offices, and such prior art may prevent issuance of claims that would provide us with a competitive advantage. We cannot be certain that we and respective patent offices have identified all relevant prior art at the time of issuance, and later identification of undiscovered prior art may provide basis for later invalidating our issued patent claims. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to the treatment of 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 MAA is currently generally protected as confidential information, the EMA and national regulatory authorities may disclose much of the nonclinical and clinical information in MAAs, including the full clinical trial reports, in response to freedom of information requests after the marketing authorization has been granted. Similarly, as of January 31, 2022 under the EU Clinical Trials Regulation (EU) No 536/2014, the EU clinical trials information system allows the public to access MAA data submitted to the EMA or national regulatory authorities (excluding any commercially confidential information). There may be a risk that information that we consider to be trade secrets or other proprietary information becomes publicly available, including to our competitors, under such transparency requirements in the EU.

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

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

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

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

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

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

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

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

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

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

- the scope of rights granted under the Menarini License and other interpretation-related issues;
- the extent to which Menarini's technology and processes infringe our intellectual property that is not subject to the Menarini License;
- claims that our technology infringes third-party intellectual property;
- the sublicensing of patent and other rights;
- our diligence obligations and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property.

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

Risks Related to Government Regulation

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

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

For example, in March 2010, President Obama signed into law the 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 ("IRA") into law, which sets forth meaningful changes to drug product reimbursement by Medicare. Among other actions, the IRA permits U.S. Department of Health and Human Services ("HHS") to engage in price-capped negotiation to set the price of certain drugs and biologics reimbursed under Medicare Part B and Part D. The IRA contains statutory exclusions to the negotiation program, including for certain orphan designated drugs for which the only approved indication (or indications) is for the orphan disease or condition. Should our product candidates be approved and covered by Medicare Part B or Part D, and fail to fall within a statutory exclusion, such as that for an orphan drug, those products could, after a period of time, be selected for negotiation and become subject to prices representing a significant discount from average prices to wholesalers and direct purchasers. The IRA also establishes a rebate obligation for drug manufacturers that increase prices of Medicare Part B and Part D covered drugs at a rate greater than the rate of inflation. The inflation rebates may require us to pay rebates if we increased the cost of a covered Medicare Part B or Part D approved product faster than the rate of inflation. In addition, the law eliminates the "donut hole" under Medicare Part D beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees' prescription costs for brand drugs below the out-of-pocket maximum and 20% once the out-of-pocket maximum has been reached. Our cost-sharing responsibility for any approved product covered by Medicare Part D could be significantly greater under the newly designed Part D benefit structure compared to the pre-IRA benefit design. Additionally, manufacturers that fail to comply with certain provisions of the IRA may be subject to penalties, including civil monetary penalties. The IRA is anticipated to have significant effects on the pharmaceutical industry and may reduce the prices we can charge and reimbursement we can receive for our products, among other effects.

In addition, other federal health reform measures have been proposed and adopted in the United States since the ACA was enacted. For example, as a result of the Budget Control Act of 2011, providers are subject to Medicare payment reductions of 2% per fiscal year, which went into effect on April 1, 2013. This 2% reduction was temporarily suspended during the COVID-19 pandemic, but has since been reinstated and, unless Congress and/or the Executive Branch take additional action, will begin to increase gradually starting in April 2030, reaching 4% in April 2031, until sequestration ends in October 2031. Further, the American Taxpayer Relief Act of 2012 reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments from providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015 also introduced a quality payment program under which certain individual Medicare providers will be subject to certain incentives or penalties based on new program quality standards. In November 2019, CMS issued a final rule finalizing the changes to the Medicare Quality Payment Program. On May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted

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

On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate price cap, currently set at 100% of a drug's average manufacturer price for single source and innovator multiple source products, beginning on January 1, 2024. Further, in July 2021, the Biden administration released an executive order that included multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug price reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions by HHS. No legislative or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of the budget reconciliation process. Additionally, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subjects drug manufacturers to civil monetary penalties and a potential excise tax for offering a price that is not equal to or less than the negotiated "maximum fair price" under the law, and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. Nonetheless, since CMS may establish a maximum price for these products in price negotiations, we would be fully at risk of government action if our products are the subject of Medicare price negotiations. Moreover, given the risk that could be the case, these provisions of the IRA may also further heighten the risk that we would not be able to achieve the expected return on our drug products or full value of our patents protecting our products if prices are set after such products have been on the market for nine years.

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

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

Although we cannot predict the full effect on our business of the implementation of existing legislation or the enactment of additional legislation pursuant to healthcare and other legislative reform, we believe that legislation or regulations that would reduce reimbursement for, or restrict coverage of, obicetrapib, if approved, or any of our future products could adversely affect how much or under what circumstances healthcare providers will prescribe or administer our products. This could adversely affect our business by reducing our ability to generate revenues, raise capital, obtain licenses and market our products. In addition, we believe the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of pharmaceutical products, which may adversely impact product sales.

In April 2023, the EU Commission released proposals to amend the current EU pharmaceutical regulatory framework. The potential reforms include shortening the periods of regulatory and/or marketing protections available for innovative products. Depending on the final wording of these reforms (if adopted), a reduction in the periods of regulatory and/or marketing protections available for obicetrapib or any of our future product candidates may adversely affect the commercial viability of such products in the EU. These changes could adversely affect our business by reducing our protection against generic competitors entering the EU market. Depending on the progress of the EU Parliament

and Council, changes to EU pharmaceutical legislation are not expected to come into force until 2025 or 2026 at the earliest and additional transitional periods mean that the changes will most likely not take effect until 2027 or 2028.

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

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

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

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

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

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

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

Our operations will also be subject to the federal transparency requirements under the ACA, which require certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to annually report to the CMS an agency within HHS information related to payments and other transfers of value provided to physicians, teaching hospitals, certain ownership and investment interests held by physicians and their immediate family members and certain non-physician providers (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified-nurse midwives). On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation ("MFN") executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation, challenging the MFN model on August 10, 2021, CMS published a proposed rule that seeks to rescind the MFN model interim rule. In addition, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate price cap, currently set at 100% of a drug's average manufacturer price for single source and innovator multiple source products, beginning on January 1, 2024. Further, in July 2021, the Biden administration released an executive order that included multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug price reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions by HHS. No legislative or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of the budget reconciliation process. Additionally, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less

than the negotiated "maximum fair price" under the law, and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges.

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

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

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

EU data protection laws including the European 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 the federal Health Insurance Portability and Accountability Act of 1996 ("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 HHS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors often follow CMS. It is difficult to predict what CMS as well as other payors will decide with respect to reimbursement.

Reimbursement may impact the demand for, and/or the price of, any product for which we obtain marketing approval. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA, the EMA or other comparable

regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution.

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

•a covered benefit under its health plan;

•safe, effective and medically necessary;

•appropriate for the specific patient;

•cost-effective; and

•neither experimental nor investigational.

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

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

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

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

In the EU, the requirements governing drug pricing and reimbursement vary widely between EU member states. Some EU member states provide that products may be marketed only after a reimbursement price has been agreed. Some EU member states may require the completion of additional studies that compare the cost effectiveness of a particular product candidate to currently available therapies (so called health technology assessments) in order to obtain reimbursement or pricing approval. Moreover, at the national level, EU member states may restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU member states may approve a specific price for a product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU member states allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many EU member states have increased the amount of discounts required on pharmaceuticals and these efforts could continue as EU member states attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the EU. The downward pressure on health care costs in general, particularly prescription products, has become significant. As a result, increasingly high barriers are being erected to the entry of new products in the marketplace. Political, economic and regulatory developments in the EU may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel trade (arbitrage between low-priced and high-priced member states) can further reduce prices. Acceptance of any medicinal product for reimbursement may come with cost, use and often volume restrictions, which again can vary by country. In addition, results based rules of reimbursement may apply. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales and the potential profitability of any of our product candidates in those countries would be negatively affected. In April 2023, the EU Commission released proposals to amend the current EU pharmaceutical regulatory framework. The potential reforms, if adopted, and depending on their final form, may cause additional pressure on pricing issues

across the EU. For example, certain additional periods of regulatory exclusivity will only be available to medicinal products that are released and continuously supplied in a sufficient quantity and in the presentations necessary to cover the needs of the patients in every member state within two years of authorization (for products authorized through the centralized procedure). The potential commercial value of such a benefit may disproportionately affect pricing negotiations in member states that may otherwise be lower priority markets. However, the EU Parliament and Council are yet to agree on the final wording of any proposed legislation. Depending on the progress of the EU Parliament and Council, any changes to EU pharmaceutical legislation are not expected to come into force until 2025 or 2026 at the earliest. Additional transitional periods mean that the changes will most likely not take effect until 2027 or 2028.

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

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

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

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

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

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

Risks Related to Our Financial Position

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

Our ability to utilize tax losses and tax loss carryforwards is conditioned upon it attaining profitability and generating taxable income. We have incurred significant tax losses since inception and it is anticipated that we will continue to incur significant losses. As of December 31, 2023, we disclosed unused tax losses of $301.1 million. Additionally, our ability to utilize tax losses and tax loss carryforwards to offset future taxable income may be subject to certain limitations. In this respect, as of January 1, 2022, tax losses can be carried back one year and carried forward indefinitely in the Netherlands. However, both the carry back and carry forward tax loss relief will be limited to 50% of the taxable profit to the extent it exceeds EUR 1 million, calculated per financial year. As a result of transitional law, tax losses incurred in the financial years that started on or after January 1, 2013 (our oldest tax loss year as of December 31, 2023) and that are still available for carry forward as of January 1, 2024 also fall under the new scheme that entered into effect on January 1, 2022 and will therefore be indefinite. In addition, pursuant to Article 20a of the Dutch Corporate Income Tax, tax loss carryforwards can no longer be offset against future taxable profits if the ultimate ownership in a Dutch taxpayer has changed by an amount equal to or greater than 30%, unless certain counter evidence rules are met. In this respect, we believe and have taken the position that the tax losses of NewAmsterdam Pharma B.V. available for carry forward have not

been forfeited as a result of the change of ownership back in 2020, when NewAmsterdam Pharma acquired all shares in the capital of NewAmsterdam Pharma B.V. (formerly Dezima Pharma B.V.), and that the tax losses of NewAmsterdam Pharma and NewAmsterdam Pharma B.V. have not been forfeited as a result of the Business Combination. On May 25, 2022, we filed a ruling request with the Dutch Tax Authorities to confirm that the change of ownership back in 2020 (described above) did not result in the loss of the tax losses of NewAmsterdam Pharma B.V. available for carry forward at that time. However, as of the date hereof, the Dutch Tax Authorities had not yet decided on our request. We currently expect, but can in no way guarantee or enforce, that the Dutch Tax Authority will grant our request.

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

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

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

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

Based on current estimates of the composition of the income and assets of the Company and its subsidiaries for the taxable year ended December 31, 2023, we believe that the Company may be treated as a passive foreign investment company ("PFIC") for U.S. federal income tax purposes for the 2023 taxable year. We have not yet determined whether we expect to be a PFIC for any future taxable years. Under the U.S. Internal Revenue Code of 1986, as amended (the "Code"), a non-U.S. corporation is classified as a PFIC for U.S. federal income tax purposes in the applicable tax year if, after the application of certain "look-through" rules with respect to subsidiaries, (i) at least 75% of its gross income in a taxable year, including its pro rata share of the gross income of any corporation in which it is considered to own at least 25% of the shares by value, is "passive income" or (ii) at least 50% of the value of its assets in a taxable year, ordinarily determined on the basis of quarterly averages, is attributable to assets that produce or are held for the production of "passive income." The determination of whether the Company or any of its non-U.S. subsidiaries is a PFIC is made annually and thus subject to change, and it generally cannot be made until the end of the taxable year.

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

A U.S. Holder (as defined below) generally will be subject to additional U.S. federal income taxes and interest charges on the gain from a sale of Ordinary Shares or the warrants to purchase Ordinary Shares initially issued as part of the FLAC initial public offering (the "Public Warrants"), and the warrants to purchase Ordinary Shares initially issued as part of a unit issued in a private placement concurrently with the closing of FLAC's initial public offering (the "Private Placement Warrants," and together with the Public Warrants, 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.

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

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

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

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

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

Risks Related to Ownership of Our Securities

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

We filed a registration statement on Form F-1 (Registration No. 333-268888), as most recently amended by the post-effective amendment No. 3 on Form S-3, registering up to 60,395,006 Ordinary Shares (the "Resale Shares") for resale by certain of our securityholders. The Resale Shares represent a substantial percentage of our outstanding Ordinary Shares and Warrants, and the sales of such securities, or the perception that those sales might occur, could depress the market price of our Ordinary Shares and Warrants and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our Ordinary Shares and Warrants but the sale of a large number of securities could result in a significant decline in the public trading price of our securities.

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

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

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

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

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

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

- the realization of any of the risk factors presented in herein;
- adverse results, or perceived adverse results, or delays in our clinical trials,
- additions and departures of key personnel;
- failure to comply with the requirements of Nasdaq;
- failure to comply with the Sarbanes-Oxley Act of 2002 ("Sarbanes-Oxley") or other laws or regulations;
- future issuances, sales, resales or repurchases or anticipated issuances, sales, resales or repurchases, of Ordinary Shares, including due to the expiration of contractual lock-up agreements;
- publication of research reports about the Company;
- failure to meet expectations of investors or securities analysts;
- the performance and market valuations of other similar companies;
- new laws, regulations, subsidies, or credits or new interpretations of existing laws applicable to the Company;
- commencement of, or involvement in, litigation involving the Company;
- broad disruptions in the financial markets, including sudden disruptions in the credit markets;

•speculation in the press or investment community;

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

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

•changes in accounting principles, policies and guidelines;

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

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

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

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

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

•a limited availability of market quotations for our securities;

•reduced liquidity for our securities;

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

•a limited amount of analyst coverage; and

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

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

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

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

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

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

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

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

Our management team has limited experience managing a public company.

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

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

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

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

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

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

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

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

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

****Our principal stockholders and management own a significant percentage of our common stock, have representation on the Board of Directors and will be able to control matters subject to shareholder approval.***

As of September 30, 2024, our executive officers, directors and holders of 5% or more of our capital stock beneficially owned approximately 55.5% of our outstanding Ordinary Shares (assuming that none of the 1,886,137 Earnout Shares have been issued). Certain of our directors are also affiliated with certain of our greater than 5% shareholders. As a result of the foregoing, these shareholders may be able to significantly influence the outcome of matters submitted for director action, subject to obligation of the Board of Directors to act in the interest of all of our stakeholders, and for shareholder action, including the designation and appointment of the Board of Directors and approval of significant corporate transactions, including business combinations, consolidations and mergers. The influence of these shareholders over our management could have the effect of delaying or preventing a change in control or otherwise discouraging a potential acquirer from attempting to obtain control of the Company, which could cause the market price of our Ordinary Shares to decline or prevent our shareholders from realizing a premium over the market price for their Ordinary Shares. Investors in our Ordinary Shares should consider that the interests of these shareholders may differ from their interests in material respects.

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

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

We are required to disclose changes made in our internal controls and procedures on an annual basis and our management will be required to assess the effectiveness of these controls annually beginning with our fiscal year ending December 31, 2023. However, for as long as we are an "emerging growth company" under the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"), our independent registered

public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404(b) of Sarbanes-Oxley. Because the market value of our Ordinary Shares held by non-affiliates exceeded $700 million as of June 30, 2024, we will cease to qualify as an emerging growth company as of December 31, 2024 after which our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

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

We have identified material weaknesses in our internal control over financial reporting. 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, 2023, 2022 and 2021 and three and nine months ended September 30, 2024 and 2023, our management identified material weaknesses in the design of our internal control over financial reporting across the principles for each component of the COSO framework at the entity level (i.e. control environment, risk assessment, monitoring, information & communication and control activities) and accordingly, across its business and IT processes. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be detected or prevented on a timely basis. Specifically, the material weaknesses that were identified, individually or in the aggregate, included the following:

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

As a result of the material weaknesses in our internal controls over financial reporting, our management has concluded that as of December 31, 2023 and September 30, 2024, our disclosure controls and procedures were not effective. As described in more detail in the section titled "*Controls and Procedures—Evaluation of Disclosure Controls and Procedures*", our management, under the oversight of the Audit Committee, has begun taking steps in an effort to remediate the identified material weaknesses, which steps consist primarily of engaging additional personnel and establishing the internal control framework. We are continuing to evaluate additional controls and procedures that may be required to remediate the identified material weaknesses. Our identified material weaknesses will not be considered remediated until the applicable controls operate for a sufficient period of time and the management has concluded, through testing, that these controls are operating effectively.

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 if we 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.

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

We have the ability to redeem all outstanding Warrants at any time after they become exercisable and prior to their expiration, at a price of $0.01 per warrant, if, among other things, the closing price of the Ordinary Shares equals or exceeds $18.00 per share (as adjusted for share sub-divisions, share capitalizations, reorganizations, recapitalizations and the like) for any 20 trading days within a 30-trading day period ending on the third trading day prior to the date on which notice of the redemption is given to the warrant holders (the "Reference Value"). If and when the Warrants become redeemable by us, we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws. Redemption of the outstanding Warrants as described above could force you to (i) exercise your Warrants and pay the exercise price therefor at a time when it may be disadvantageous for you to do so, (ii) sell your Warrants at the then-current market price when you might otherwise wish to hold your Warrants or (iii) accept the nominal redemption price which, at the time the outstanding Warrants are called for redemption, is likely to be substantially less than the market value of your Warrants.

None of the Private Placement Warrants will be redeemable by us so long as they are held by Frazier Lifesciences Sponsor LLC or its permitted transferees.

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

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

As of September 30, 2024, we had Warrants to purchase an aggregate of 2,700,152 Ordinary Shares and Pre-Funded Warrants to purchase an aggregate of 4,736,841 Ordinary Shares outstanding. The exercise price of the Warrants and Pre-Funded Warrants is $11.50 per share and $0.0001 per share, respectively. To the extent such warrants are exercised, additional Ordinary Shares will be issued, which will result in dilution to the holders of Ordinary Shares and increase the number of Ordinary Shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market or the fact that such Warrants and Pre-Funded Warrants may be exercised could adversely affect the market price of Ordinary Shares. To the extent that the Warrants are "out-of-the-money" we do not expect that all of the Warrant holders will exercise their Warrants. As such, there is no guarantee that the Warrants will ever be exercised. As of September 30, 2024, there were 20,180,954 shares issuable upon the exercise of options granted under the LTIP, Rollover Plan, Supplementary LTIP and Inducement Plan at a weighted average exercise price of $9.68. If the options are exercised, there may be additional Ordinary Shares offered which may further adversely affect the market price of our Ordinary Shares.

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

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

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

The Warrant Assumption Agreement provides that (i) the terms of the Warrants may be amended without the consent of any holder for the purpose of (a) curing any ambiguity or correct any mistake, including to conform the provisions of the Warrant Assumption Agreement to the description of the terms of such warrants and the Warrant Assumption Agreement set forth in the Annual Report, or defective provision, (b) amending the definition of "Ordinary Cash Dividend" as contemplated by and in accordance with the Warrant Assumption Agreement or (c) adding or changing any provisions with respect to matters or questions arising under the Warrant Assumption Agreement as the parties to the Warrant Assumption Agreement may deem necessary or desirable and that the parties deem to not adversely affect the rights of the registered holders of such warrants under the Warrant Assumption Agreement and (ii) all other modifications or amendments require the vote or written consent of at least 65% of the then outstanding Public Warrants; provided that any amendment that solely affects the terms of the Private Placement Warrants or any provision of the Warrant Assumption Agreement solely with respect to the Private Placement Warrants will require at least 50% of the then outstanding Private Placement Warrants. Accordingly, we may amend the terms of the Public Warrants in a manner adverse to a holder if holders of at least 65% of the then outstanding Public Warrants approve of such amendment. Although the ability to amend the terms of the Public Warrants with the consent of at least 65% of the then outstanding Public Warrants is unlimited, examples of such amendments could be amendments to, among other things, increase the exercise price of the warrants, shorten the exercise period or decrease the number of Ordinary Shares purchasable upon exercise of a warrant.

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

The Warrant Assumption Agreement provides that, subject to applicable law, (i) any action, proceeding or claim against us arising out of or relating in any way to the Warrant Assumption Agreement, including under the Securities Act, will be brought and enforced in the courts of

the State of New York or the United States District Court for the Southern District of New York, and (ii) that we will irrevocably submit to such jurisdiction, which jurisdiction will be the exclusive forum for any such action, proceeding or claim.

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

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

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

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

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

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

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

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

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

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

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

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

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

- the Board of Directors, in light of the circumstances at hand when the cooling-off period was invoked, could not reasonably have concluded that the relevant proposal or hostile offer constituted a material conflict with the interests of us and our business;
- the Board of Directors cannot reasonably believe that a continuation of the cooling-off period would contribute to careful policy-making; or
- other defensive measures, having the same purpose, nature and scope as the cooling-off period, have been activated during the cooling-off period and have not since been terminated or suspended within a reasonable period at the relevant shareholders' request (i.e., no "stacking" of defensive measures).

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

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

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

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

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

We currently qualify as an emerging growth company within the meaning of Section 2(a) of the Securities Act, as modified by the JOBS Act, and if we take 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. Because the market value of our Ordinary Shares held by non-affiliates exceeded $700 million as of June 30, 2024, we will cease to qualify as an emerging growth company as of December 31, 2024.

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. We intend to take advantage of this extended transition period under the JOBS Act for adopting new or revised financial accounting standards.

For as long as we continue to be an emerging growth company, we 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 Sarbanes-Oxley, and reduced disclosure obligations regarding executive compensation in our 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.

As a result of our expected loss of emerging growth company status, we will no longer be able to take advantage of any of the exemptions from various reporting requirements that are applicable to emerging growth companies set forth above and will be subject to more stringent reporting and compliance requirements. We expect that the loss of our emerging growth company status and compliance with these additional requirements will substantially increase our legal and financial compliance costs. In addition, any failure to comply with these additional requirements in a timely manner, or at all, could have an adverse effect on our business and results of operations and could cause a decline in the price of our common stock.

We cannot predict if investors will find Ordinary Shares less attractive because we have relied 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 while still available to us. 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 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Rule 10b5-1 Trading Arrangements

Except as set forth below, during the three months ended September 30, 2024, none of our officers or directors adopted, amended or terminated a "Rule 10b5-1 trading arrangement," as defined in Item 408(c) of Regulation S-K, each of which is intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act.

On September 20, 2024, Douglas Kling, our Chief Operating Officer, terminated a Rule 10b5-1 trading arrangement for the potential sale of up to 431,144 Ordinary Shares. The arrangement was initially adopted on March 29, 2024.

On September 25, 2024, Louise Kooij, our Chief Accounting Officer terminated a Rule 10b5-1 trading arrangement for the potential sale of up to 213,073 Ordinary Shares. The arrangement was initially adopted on June 27, 2024.

On September 26, 2024, Douglas Kling, our Chief Operating Officer, adopted a Rule 10b5-1 trading arrangement for the potential sale of up to 798,612 Ordinary Shares, subject to certain price thresholds and other conditions. The arrangement's expiration date is September 26, 2025.

On September 27, 2024, Ian Somaiya, our Chief Financial Officer, adopted a Rule 10b5-1 trading arrangement for the potential sale of up to 200,000 Ordinary Shares, subject to certain price thresholds and other conditions. The arrangement's expiration date is September 30, 2025.

On September 27, 2024, Louise, Kooij, our Chief Accounting Officer, adopted a Rule 10b5-1 trading arrangement for the potential sale of up to 110,000 Ordinary Shares, subject to certain price thresholds and other conditions. The arrangement's expiration date is September 30, 2025.

There were no "non-Rule 10b5-1 trading arrangements," as defined in Item 408(c) of Regulation S-K, entered into or terminated during the three months ended September 30, 2024.

Item 6. Exhibits.

Exhibit No.	Description of Document	Incorporated by Reference to Filings Indicated				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	English translation of the Deed of Conversion and Articles of Association of NewAmsterdam Pharma Company N.V.	20-F	001-41562	1.1	11/28/22	
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	Inline XBRL Instance Document					X
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents					X
104	Cover Page Interactive Data File-the cover page interactive data is embedded within the Inline XBRL document or included within the Exhibit 101 attachments					X

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

NewAmsterdam Pharma Company N.V.

Date: November 6, 2024

By: /s/ Michael Davidson
Michael Davidson, M.D.
Chief Executive Officer and Director
(Principal Executive Officer)

Date: November 6, 2024

By: /s/ Ian Somaiya
Ian Somaiya
Chief Financial Officer
(Principal Financial Officer)