Table of Contents

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 June 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: 001-39712

OLEMA PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**30-0409740**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
780 Brannan Street **San Francisco, CA**	**94103**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (415) 651-3316

N/A

(Former name, former address and former fiscal year, if changed since last report)

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

Title of Each Class of Securities Registered	Trading Symbol	Name of Each Exchange on which Securities are Registered
Common Stock, par value $0.0001 per share	OLMA	The Nasdaq Global Select Market

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 August 2, 2024, the number of outstanding shares of the Registrant's common stock was 57,266,358.

Table of Contents

PART I-FINANCIAL INFORMATION

Item 1. Financial Statements.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements.

Olema Pharmaceuticals, Inc.

Condensed Consolidated Balance Sheets
(Unaudited)
(Amounts in thousands, except for share amounts)

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 16,892	$ 68,539
Marketable securities	222,212	193,268
Prepaid expenses and other current assets	3,083	4,706
Total current assets	242,187	266,513
Operating lease right-of-use assets	1,814	2,291
Other assets and long-term deposits	10,556	8,141
Total assets	$ 254,557	$ 276,945
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,354	$ 2,698
Operating lease liabilities, current	1,103	988
Other current liabilities	21,078	17,935
Total current liabilities	26,535	21,621
Operating lease liabilities, net of current portion	859	1,429
Total liabilities	27,394	23,050
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of June 30, 2024 and December 31, 2023; no shares issued and outstanding as of June 30, 2024 and December 31, 2023.	—	—
Common stock, $0.0001 par value; 490,000,000 shares authorized as of June 30, 2024 and December 31, 2023; 57,258,367 and 55,097,118 shares issued as of June 30, 2024 and December 31, 2023, respectively; 57,246,411 and 54,992,784 shares outstanding as of June 30, 2024 and December 31, 2023, respectively.	4	4
Additional paid-in capital	594,261	559,176
Accumulated other comprehensive (loss) income	(118)	347
Accumulated deficit	(366,984)	(305,632)
Total stockholders' equity	227,163	253,895
Total liabilities and stockholders' equity	$ 254,557	$ 276,945

See accompanying notes to the condensed consolidated financial statements.

Olema Pharmaceuticals, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(Amounts in thousands, except for share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 29,109	$ 17,989	$ 58,992	$ 40,815
General and administrative	4,421	3,612	8,877	10,388
Total operating expenses	33,530	21,601	67,869	51,203
Loss from operations	(33,530)	(21,601)	(67,869)	(51,203)
Other income:				
Interest income	3,108	1,550	6,460	2,855
Other income (expense)	40	(44)	57	(33)
Total other income	3,148	1,506	6,517	2,822
Net loss	$ (30,382)	$ (20,095)	$ (61,352)	$ (48,381)
Net loss per share, basic and diluted	$ (0.54)	$ (0.49)	$ (1.10)	$ (1.20)
Weighted average shares used to compute net loss per share, basic and diluted	56,282,402	40,720,294	55,928,363	40,470,041

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Net loss	$ (30,382)	$ (20,095)	$ (61,352)	$ (48,381)
Other comprehensive (loss) income:				
Net unrealized (loss) gain on marketable securities	(108)	460	(465)	1,295
Total comprehensive loss	$ (30,490)	$ (19,635)	$ (61,817)	$ (47,086)

See accompanying notes to the condensed consolidated financial statements.

Olema Pharmaceuticals, Inc.

Condensed Consolidated Statements of Stockholders' Equity (Unaudited)
(Amounts in thousands, except for share amounts)

	Three Months Ended June 30, 2024					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at March 31, 2024	55,867,863	$ 4	$ 572,926	$ (10)	(336,602)	$ 236,318
Issuance of shares under at-the-market offering, net of issuance costs of $25	1,225,952	—	14,886	—	—	14,886
Stock-based compensation expense	—	—	5,542	—	—	5,542
Issuance of shares under the employee stock purchase plan	70,701	—	650	—	—	650
Employee stock purchase plan expense	—	—	182	—	—	182
Exercise of stock options	29,587	—	75	—	—	75
Vesting of restricted stock awards	52,308	—	—	—	—	—
Net unrealized loss on marketable securities	—	—	—	(108)	—	(108)
Net loss	—	—	—	—	(30,382)	(30,382)
Balances at June 30, 2024	57,246,411	$ 4	$ 594,261	$ (118)	(366,984)	$ 227,163

	Six Months Ended June 30, 2024					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2023	54,992,784	$ 4	$ 559,176	$ 347	(305,632)	$ 253,895
Issuance of shares under at-the-market offering, net of issuance costs of $166	1,772,278	—	22,787	—	—	22,787
Stock-based compensation expense	—	—	10,246	—	—	10,246
Exercise of stock options	317,989	—	1,015	—	—	1,015
Issuance of shares under the employee stock purchase plan	70,701	—	650	—	—	650
Employee stock purchase plan expense	—	—	387	—	—	387
Vesting of restricted stock awards	92,659	—	—	—	—	—
Net unrealized loss on marketable securities	—	—	—	(465)	—	(465)
Net loss	—	—	—	—	(61,352)	(61,352)
Balances at June 30, 2024	57,246,411	$ 4	$ 594,261	$ (118)	(366,984)	$ 227,163

Olema Pharmaceuticals, Inc.

Condensed Consolidated Statements of Stockholders' Equity (Unaudited)
(Amounts in thousands, except for share amounts)

	Three Months Ended June 30, 2023					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at March 31, 2023	40,438,320	$ 3	$ 413,213	$ (978)	$ (237,263)	$ 174,975
Stock-based compensation expense	—	—	4,040	—	—	4,040
Exercise of stock options	357,312	—	1,332	—	—	1,332
Issuance of shares under the employee stock purchase plan	270,541	—	711	—	—	711
Employee stock purchase plan expense	—	—	130	—	—	130
Vesting of early exercised stock options	6,990	—	30	—	—	30
Vesting of restricted stock awards	49,319	—	—	—	—	—
Net unrealized gain on marketable securities	—	—	—	460	—	460
Net loss	—	—	—	—	(20,095)	(20,095)
Balances at June 30, 2023	41,122,482	$ 3	$ 419,456	$ (518)	(257,358)	$ 161,583

	Six Months Ended June 30, 2023					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2022	40,287,097	$ 3	$ 408,333	$ (1,813)	$ (208,977)	$ 197,546
Stock-based compensation expense	—	—	8,555	—	—	8,555
Exercise of stock options	452,227	—	1,552	—	—	1,552
Issuance of shares under the employee stock purchase plan	270,541	—	711	—	—	711
Employee stock purchase plan expense	—	—	245	—	—	245
Vesting of early exercised stock options	13,980	—	60	—	—	60
Vesting of restricted stock awards	98,637	—	—	—	—	—
Net unrealized gain on marketable securities	—	—	—	1,295	—	1,295
Net loss	—	—	—	—	(48,381)	(48,381)
Balances at June 30, 2023	41,122,482	$ 3	$ 419,456	$ (518)	(257,358)	$ 161,583

See accompanying notes to the condensed consolidated financial statements.

Olema Pharmaceuticals, Inc.

Condensed Consolidated Statements of Cash Flows
(unaudited)
(Amounts in thousands)

	Six Months Ended June 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (61,352)	$ (48,381)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	182	199
Non-cash lease expense	575	653
Non-cash interest income on marketable securities	(4,546)	(1,972)
Loss on sale of equipment	—	8
Stock-based compensation expense, including employee stock purchase plan expense	10,633	8,800
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,623	413
Other assets and long-term deposits	(2,422)	(133)
Accounts payable	1,656	1,251
Other current liabilities	3,153	(2,692)
Operating lease liabilities	(553)	(653)
Net cash used in operating activities	(51,051)	(42,507)
Cash flows from investing activities:		
Purchase of equipment	(159)	—
Maturities of marketable securities	133,391	126,260
Purchases of marketable securities	(158,254)	(74,760)
Net cash (used in) provided by investing activities	(25,022)	51,500
Cash flows from financing activities:		
Issuance of shares under at-the-market offering, net of issuance costs of $166	22,787	—
Proceeds from exercise of stock options	989	1,552
Proceeds from issuance of common stock under employee stock purchase plan	650	711
Net cash provided by financing activities	24,426	2,263
Net (decrease) increase in cash and cash equivalents	(51,647)	11,256
Cash and cash equivalents at beginning of period	68,539	23,702
Cash and cash equivalents at end of period	$ 16,892	$ 34,958

See accompanying notes to the condensed consolidated financial statements.

Olema Pharmaceuticals, Inc.
Notes to condensed consolidated financial statements

(Unaudited)

1.Nature of the Business and Basis of Presentation

Olema Pharmaceuticals, Inc. (“Olema” or the “Company”) is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of next-generation targeted therapies for women’s cancers. The Company is advancing a pipeline of novel therapies by leveraging its deep understanding of endocrine-driven cancers, nuclear receptors, and mechanisms of acquired resistance. The Company's wholly-owned, lead product candidate, palazestrant (OP-1250), is a novel, orally-available small molecule with dual activity as both a complete estrogen receptor ("ER") antagonist ("CERAN") and selective ER degrader ("SERD"). In addition to its lead product candidate, Olema is developing a potent KAT6 inhibitor (OP-3136).

The Company is located in San Francisco, California, and was incorporated in Delaware on August 7, 2006, under the legal name of CombiThera, Inc., and on March 25, 2009, was renamed Olema Pharmaceuticals, Inc. The Company’s principal operations are based in San Francisco, California, and it has operations in Cambridge, Massachusetts. Olema Oncology Australia Pty Ltd was incorporated on January 6, 2021, and is a wholly-owned subsidiary of the Company (collectively with Olema Pharmaceuticals, Inc., referred to as “Olema” or the “Company” herein). It operates in one business segment and therefore has only one reportable segment. The Company is subject to risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including, but not limited to, successful discovery and development of its product candidates, development by competitors of new technological innovations, dependence on key personnel, the ability to attract and retain qualified employees, protection of proprietary technology, compliance with governmental regulations, the impact of geopolitical and macroeconomic events discussed in further detail below, the ability to secure additional capital to fund operations and commercial success of its product candidates. Palazestrant, OP-3136 and any future product candidates the Company may develop will require extensive non-clinical and clinical testing and regulatory approval 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.

Liquidity

The Company had $239.1 million of cash, cash equivalents and marketable securities at June 30, 2024, in addition to an available balance of $25.0 million under the Loan and Security Agreement (the "Original Loan Agreement"), dated September 5, 2023 by and between the Company, as borrower, and Silicon Valley Bank, a division of First-Citizens Bank & Trust Company (the “Bank”), as amended by the First Amendment to Loan and Security Agreement, dated June 28, 2024, by and between the Company and the Bank (the "Amendment," and the Original Loan Agreement as amended by the Amendment, the "Loan Agreement"). See Footnote 10. Commitments and Contingencies for details. Management believes that the Company’s cash, cash equivalents, marketable securities, and the amounts available under the Loan Agreement will be sufficient to fund the Company’s current operating plan for at least the next 12 months from the filing date of these condensed consolidated financial statements.

At-The-Market Offering

On January 5, 2024, the Company entered into a sales agreement (the “Sales Agreement”) with Cowen and Company, LLC (“TD Cowen”) as sales agent, pursuant to which the Company may offer and sell, from time to time, shares of our common stock, having an aggregate offering price of up to $150.0 million (the “ATM Shares”). The sales of the ATM Shares will be made by any method permitted that is deemed to be an "at-the-market" equity offering as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended ("Securities Act"), including sales made directly on or through the Nasdaq Global Select Market. The Company has agreed to pay TD Cowen a commission of up to 3.0% of the aggregate gross proceeds from any ATM Shares sold by TD Cowen.

During the three months ended June 30, 2024, the Company issued 1,225,952 shares of its common stock under the Sales Agreement at a weighted-average price of $12.39 per share for net proceeds of $14.9 million after deducting related issuance costs. During the six months ended June 30, 2024, the Company issued 1,772,278 shares of its common stock under the Sales Agreement at a weighted-average price of $13.19 for net proceeds of $22.8 million after deducting related issuance costs. As of June 30, 2024, approximately $126.6 million remained available for issuance under the Sales Agreement.

Impact of Geopolitical and Macroeconomic Events

Global economic and business activities continue to face widespread geopolitical and macroeconomic uncertainties, including labor shortages, inflation rates and the responses by central banking authorities to control such inflation, monetary supply shifts and related financial market risks and instability, recession risks, as well as potential disruptions from the Russia-Ukraine conflict and armed conflict between Israel and groups based in surrounding regions, all of which have resulted in volatility in the U.S. and global financial markets and which have led to, and may continue to lead to, additional disruptions to trade, commerce, pricing stability, credit availability and supply chain continuity globally. The extent of the impact of these factors on the Company's operational and financial performance, including its ability to execute its business strategies and initiatives in the expected time frame, will depend on future developments, which are uncertain and cannot be predicted. Any continued or renewed disruption resulting from these factors could negatively impact the Company's business. The Company continues to monitor the impact of these geopolitical and macroeconomic factors on its results of operations, financial condition and cash flows.

2.Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying interim unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP") and applicable rules and regulations of the Securities and Exchange Commission (the "SEC") regarding interim financial reporting, and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. These condensed consolidated financial statements include the accounts of Olema Pharmaceuticals, Inc. and its wholly-owned subsidiary, Olema Oncology Australia Pty Ltd. All intercompany balances and transactions have been eliminated upon consolidation.

Unaudited Interim Financial Information

The interim condensed consolidated balance sheet as of June 30, 2024, and the statements of operations and comprehensive loss, and stockholders' equity for the three and six months ended June 30, 2024 and 2023, and the statements of cash flows for the six months ended June 30, 2024 and 2023 are unaudited. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual financial statements and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for the fair presentation of the Company's condensed consolidated financial statements included in this report. The financial data and the other information disclosed in these notes to the condensed consolidated financial statements related to the three- and six-month periods are also unaudited. The results of operations presented in these unaudited condensed consolidated financial statements are not necessarily indicative of the results to be expected for the year ending December 31, 2024, or for any other future annual or interim period. The condensed consolidated balance sheet as of December 31, 2023 included herein was derived from the audited financial statements as of that date. These interim condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements included in the Company's Form 10-K as filed with the SEC on March 11, 2024 (the "Annual Report").

Use of Estimates

The accompanying condensed consolidated financial statements are prepared in accordance with GAAP. The preparation of the condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the condensed consolidated financial statements and reported amounts of expenses during the reporting period. Significant areas that require management's estimates include accruals of research and development

expenses, including accrual of research contract costs, stock-based compensation assumptions, including the fair value of common stock. On an ongoing basis, the Company evaluates its estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that management believes to be reasonable under the circumstances. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents are defined as short-term, highly liquid investments with original maturities of 90 days or fewer at the date of purchase. Cash deposits are all in reputable financial institutions in the United States as of June 30, 2024, and December 31, 2023. Cash and cash equivalents consisted of cash on deposit with U.S. banks, including the Company's bank account for its Australia subsidiary, denominated in U.S. dollars and Australian dollars and investments in interest bearing money market funds.

Marketable Securities

All marketable securities have been classified as "available-for-sale" and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its investments at the time of purchase and reevaluates such designation as of each balance sheet date. Unrealized gains and losses are excluded from net loss and are reported as a component of comprehensive loss. Realized gains and losses and declines in fair value judged to be other than temporary, if any, on available-for-sale securities are included in interest income. The cost of securities sold is based on the specific-identification method. Interest earned on marketable securities is included in interest income.

The Company periodically assesses its available-for-sale marketable securities for other-than-temporary impairment. For debt securities in an unrealized loss position, the Company first considers its intent to sell, or whether it is more likely than not that the Company will be required to sell the debt securities before recovery of their amortized cost basis. If either of these criteria are met, the amortized cost basis of such debt securities is written down to fair value through other expense.

For debt securities in an unrealized loss position that do not meet the aforementioned criteria, the Company assesses whether the decline in the fair value of such debt securities has resulted from credit losses or other factors. The Company considers the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency, and any adverse conditions specifically related to the securities, among other factors. If this assessment indicates that a credit loss may exist, the Company then compares the present value of cash flows expected to be collected from such securities to their amortized cost basis. If the present value of cash flows expected to be collected is less than the amortized cost basis, a credit loss exists and an allowance for credit losses is recorded through other expense, limited by the amount that the fair value is less than the amortized cost basis. Any additional impairment not recorded through an allowance for credit losses is recognized in other comprehensive loss. The Company has not recorded any impairments for its marketable securities.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash, cash equivalents, and marketable securities. The Company invests in a variety of financial instruments and, by its policy, limits these financial instruments to high credit quality securities issued by the U.S. government, U.S. government-sponsored agencies and highly rated banks and corporations, subject to certain concentration limits. The Company's cash, cash equivalents, and marketable securities are held by financial institutions in the United States that management believes are of high credit quality. Amounts on deposit with individual banking institutions may at times exceed the limits insured by the Federal Deposit Insurance Corporation ("FDIC"); however, the Company has not experienced any losses on such deposits.

The Company's future results of operations involve a number of other risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, uncertainty of results of clinical trials and reaching milestones, uncertainty of regulatory approval of the Company's current and potential future product candidates, uncertainty of market

acceptance of the Company's product candidates, competition from substitute products and larger companies, securing and protecting proprietary technology, strategic relationships, dependence on key individuals or sole-source suppliers, and geopolitical and macroeconomic factors.

The Company's product candidates require approvals from the U.S. Food and Drug Administration ("FDA") and comparable foreign regulatory agencies prior to commercial sales in their respective jurisdictions. There can be no assurance that any product candidates will receive the necessary approvals. If the Company were denied approval, approval was delayed or the Company was unable to maintain approval for any product candidate, it could have a materially adverse impact on the Company.

Leases

The Company adopted Accounting Standard Update ("ASU") 2016-12, *Leases*, Topic 842, ("Topic 842") as of January 1, 2021. Under Topic 842, lessees are required to recognize for all leases (with the exception of short-term leases) at the commencement date: (1) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and (2) a right-of-use ("ROU") asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the condensed consolidated statements of operations and comprehensive loss.

At the inception of an arrangement, the Company determines if an arrangement is, or contains, a lease based on the facts and circumstances present in that arrangement. Lease classification, recognition, and measurement are then determined at the lease commencement date. For arrangements that contain a lease, the Company (i) identifies lease and non-lease components, (ii) determines the consideration in the contract, (iii) determines whether the lease is an operating or finance lease; and (iv) recognizes lease ROU assets and liabilities. Lease liabilities and their corresponding ROU assets are recorded based on the present value of future lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable and as such, the Company uses the incremental borrowing rate based on the information available at the lease commencement date, which represents an internally developed rate that would be incurred to borrow, on a collateralized basis, over a similar term, an amount equal to the lease payments in a similar economic environment.

Most leases include options to renew and, or terminate the lease, which can impact the lease term. The exercise of these options is at the Company's discretion. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise such options. For any lease modification, the Company reassesses the lease classification, remeasures the related lease liability using an updated discount rate that reflects the modified lease term, and adjusts the related ROU asset under the lease modification guidance under Topic 842.

The Company has operating leases for its research and development and office facilities. Fixed lease payments on operating leases are recognized over the expected term of the lease on a straight-line basis. Variable lease expenses that are not considered fixed are recognized as incurred. Fixed and variable lease expense on operating leases is recognized within operating expenses within our condensed consolidated statements of operations and comprehensive loss.

The Company elected to not apply the recognition requirements of Topic 842 to short-term leases with terms of 12 months or less. Additional information and disclosures required by Topic 842 are contained in Note 11 "Lease" in the Annual Report.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred to discover, research and develop product candidates. These costs are recorded within research and development expenses in the condensed consolidated statements of operations and include personnel expenses, stock-based compensation expenses, allocated general and administrative expenses, and external costs including fees paid to consultants and contract research organizations ("CROs") and contract manufacturing organizations ("CMOs"), in connection with non-clinical studies and clinical trials, and other related clinical trial fees, such as for investigator fees, patient screening, laboratory work, clinical trial database management, clinical trial material management and statistical compilation and analysis. Non-refundable

prepayments for goods or services that will be used or rendered for future research and development activities are recorded as prepaid expenses and other current assets. Such amounts are recognized as an expense as the goods are delivered or the related services are performed.

Costs incurred in obtaining technology licenses that do not meet the definition of a business are charged immediately to research and development expense if the technology licensed has not reached technological feasibility and has no alternative future uses.

Reimbursements of certain costs associated with research activities performed under the agreement with Novartis Institutes for BioMedical Research, Inc. ("Novartis") are recorded as a reduction of research and development expenses and as a receivable due from Novartis, which is recorded under prepaid expenses and other current assets in the accompanying condensed consolidated financial statements, as described in Note 10, Commitments and Contingencies – Clinical Collaboration and Supply Agreement.

Research Contract Costs and Accruals

The Company has from time to time entered into various research and development and other agreements with commercial firms, researchers, universities and others for provisions of goods and services. These agreements are generally cancelable, and the related costs are recorded as research and development expenses as incurred.

The Company records accruals for estimated ongoing research and development costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the projects, studies or clinical trials, including the phase or completion of events, invoices received and contracted costs. Judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ materially from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Stock-Based Compensation

Stock-based compensation cost, including grants of stock options and restricted stock awards issued under the Company's equity incentive plans and ESPP, is measured at the grant date based on the estimated fair value of the award and is recognized as an expense on a straight-line basis over the requisite service period, which is generally the vesting period. Stock-based compensation cost for performance-based restricted stock unit awards issued under the Company's equity incentive plan is measured at the grant date based on the estimated fair value of the award, which is based on the closing stock price on the grant date, and is recognized as an expense when the Company determines that it is probable that the performance goals will be achieved, which the Company assess on a quarterly basis. The Company recognizes stock compensation in accordance with ASC 718, *Compensation — Stock Compensation* ("ASC 718"). The Company's determination of the fair value of stock options with time-based vesting on the date of grant utilizes the Black-Scholes option-pricing model. The Company estimates volatility using stock prices of peer companies and its historical data, risk-free rates using the implied yield currently available on U.S. Treasury zero-coupon issues with a remaining term equal to the expected term, and dividend yield using the Company's expectations and historical data. The Company uses the simplified method to calculate the expected term of employee stock option grants. Under the simplified method, the expected term is estimated to be the mid-point between the vesting date and the contractual term of the option. For awards with graded vesting, in which specified tranches of the options vest on different dates, the Company uses a single weighted average expected life to value the entire award, which is equal to the average of the weighted average vesting period of the award and the contractual term of the award. Equity instruments issued to nonemployees are recorded at their fair value on the grant date and without subsequent remeasurement. The amount of stock-based compensation expense recognized during a period is based on the value of the portion of the awards that are ultimately expected to vest, including awards with graded vesting. As part of the requirements of ASC 718, the Company has elected to account for forfeitures of stock option grants as they occur.

Foreign Currency Transactions

The functional currency of Olema Oncology Australia Pty Ltd, the Company's wholly-owned subsidiary, is the U.S. dollar. Accordingly, all monetary assets and liabilities of the subsidiary are remeasured into U.S. dollars at the current period-end exchange rates and non-monetary assets are remeasured using historical exchange rates. Income and expense elements are remeasured to U.S. dollars using the average exchange rates in effect during the period. Remeasurement gains and losses are recorded as other income (expense) on the consolidated statements of operations.

The Company is subject to foreign currency risk with respect to its clinical and manufacturing contracts denominated in currencies other than the U.S. dollar, predominantly the Australian dollar and the Euro. Payments on contracts denominated in foreign currencies are made at the spot rate on the day of payment. Changes in the exchange rate between billing dates and payment dates are recorded within other income (expense) on the condensed consolidated statements of operations.

Net Loss Per Common Share

Basic net loss per common share is computed by dividing the net loss per common share by the weighted average number of common shares outstanding for the period without consideration of common stock equivalents. Diluted net loss per common share is computed by adjusting net loss to reallocate undistributed earnings based on the potential impact of dilutive securities, and by dividing the diluted net loss by the weighted average number of common shares outstanding for the period, including potential dilutive common shares. For purpose of this calculation, outstanding stock options, including unvested early exercised options, unvested restricted stock awards, unvested performance-based restricted stock unit awards and contingently issuable common stock related to the 2020 Employee Stock Purchase Plan (the "ESPP") are considered potential dilutive common shares. Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share for all periods as the inclusion of all potential common shares outstanding would have been anti-dilutive.

Recent Accounting Pronouncements

There were no new accounting pronouncements that were relevant to the Company as of and for the three and six months ended June 30, 2024.

3. Fair Value Measurement

The Company assesses the fair value of financial instruments based on the provisions of ASC 820, *Fair Value Measurements*. ASC 820 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

•Level 1 — Inputs are unadjusted quoted prices in active markets for identical assets or liabilities accessible to the reporting entity at the measurement date.

•Level 2 — Inputs other than quoted prices included in Level 1 that are observable for the asset or liability, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

•Level 3 — Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

(in thousands)	June 30, 2024 Level 1	Level 2	Level 3	Total
Financial Assets				
Cash	$ 2,110	$ —	$ —	$ 2,110
Money market funds	10,918	—	—	10,918
Commercial paper	—	88,804	—	88,804
Corporate bonds	—	16,460	—	16,460
U.S. government treasury bills	97,853	—	—	97,853
Government-sponsored enterprise securities	—	23,088	—	23,088
Total	$ 110,881	$ 128,352	$ —	$ 239,233

(in thousands)	December 31, 2023 Level 1	Level 2	Level 3	Total
Financial Assets				
Cash	$ 3,570	$ —	$ —	$ 3,570
Money market funds	59,280	—	—	59,280
Commercial paper	—	105,017	—	105,017
Corporate bonds		12,627		12,627
U.S. government treasury bills	60,012	—	—	60,012
Government-sponsored enterprise securities	—	21,606	—	21,606
Total	$ 122,862	$ 139,250	$ —	$ 262,112

(in thousands)	June 30, 2024 Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Financial Assets				
Cash and cash equivalents	$ 17,021	$ —	$ —	$ 17,021
Short-term marketable securities (<12 months to maturity)	201,132	15	(121)	201,026
Long-term marketable securities (>12 months to maturity)	21,198	19	(31)	21,186
Total	$ 239,351	$ 34	$ (152)	$ 239,233

(in thousands)	December 31, 2023 Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Financial Assets				
Cash and cash equivalents	$ 68,844	$ —	$ —	$ 68,844
Short-term marketable securities (<12 months to maturity)	169,966	176	(8)	170,134
Long-term marketable securities (>12 months to maturity)	22,955	179	—	23,134
Total	$ 261,765	$ 355	$ (8)	$ 262,112

The Company considers its marketable securities with maturities beyond one year as current assets, based on their highly liquid nature and because such marketable securities represent the investment of cash that is available for current operations. The Company considers its investment portfolio of marketable securities to be available-for-sale.

The Company periodically reviews its available-for-sale marketable securities for other-than-temporary impairment. The Company considers factors such as the duration, severity and the reason for the decline in value, the potential recovery period and its intent to sell. For debt securities, the Company also considers whether (i) it is more likely than not that the Company will be required to sell the debt securities before recovery of their amortized cost basis, and (ii) the amortized cost basis cannot be recovered as a result of credit losses.

There were no marketable securities that had been in a consecutive loss position for more than 12 months as of June 30, 2024. During the three and six months ended June 30, 2024, the Company did not recognize any other-than-temporary impairment loss. As of June 30, 2024, there was no allowance for losses on available-for-sale debt securities attributable to credit risk.

As of June 30, 2024, all of the Company's cash and cash equivalents consisted of cash on deposit with U.S. banks denominated in U. S. dollars and Australian dollars.

4.Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	June 30, 2024	December 31, 2023
Prepaid clinical development costs	$ 929	$ 858
Interest receivable	821	673
Prepaid subscriptions and licenses	621	255
Prepaid insurance	541	1,239
Other	171	190
Reimbursable research and development costs from a collaboration partner	—	1,491
Total	$ 3,083	$ 4,706

5.Other Assets and Long-Term Deposits

Other assets and long-term deposits consisted of the following (in thousands):

	June 30, 2024	December 31, 2023
Clinical development project deposits	$ 9,110	$ 6,688
Property and equipment, net	945	968
Security deposits	485	485
Other	16	—
Total	$ 10,556	$ 8,141

6.Accrued and Other Current Liabilities

Accrued and other current liabilities consisted of the following (in thousands):

	June 30, 2024	December 31, 2023
Accrued research and development related costs	$ 17,329	$ 11,322
Accrued employee bonuses	2,499	5,465
Accrued professional fees	793	903
Accrued payroll related costs	396	172
Accrued taxes	61	73
Total	$ 21,078	$ 17,935

7.Stock-Based Compensation

In 2014, the Company's Board of Directors (the "Board") and stockholders approved and adopted the Company's 2014 Stock Plan (the "2014 Plan"). The 2014 Plan permitted the grant of options and restricted stock awards (including restricted stock purchase rights and restricted stock bonus awards). The 2014 Plan was terminated on the date the Company's 2020 Equity Incentive Plan (the "2020 Plan"), which is described below, became effective, and since that date, no additional awards have been or will be made pursuant to the 2014 Plan. However, any outstanding awards granted under the 2014 Plan will remain outstanding, subject to the terms of the 2014 Plan award agreements, until such outstanding options are exercised or until any awards terminate or expire by their terms.

In 2020, the Board and the Company's stockholders approved and adopted the 2020 Plan. The 2020 Plan permits the grant of options, restricted stock awards, stock appreciation rights, restricted stock unit awards, performance awards, and other awards. The maximum number of shares of common stock that were initially issuable under the 2020 Plan was a number not to exceed 6,494,510 shares of the Company's common stock, which is the sum of (i) 2,152,080 new shares, plus (ii) an additional number of shares not to exceed 4,342,430 shares, consisting of any shares of the Company's common stock subject to outstanding stock options or other stock awards granted under the 2014 Plan that, on or after the date on which the 2020 Plan became effective, terminated or expired prior to exercise or settlement; were not issued because the award was settled in cash; were forfeited because of the failure to vest; or were reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price. In addition, the number of shares of the Company's common stock reserved for issuance under the 2020 Plan automatically increases on January 1 of each year for a period of ten years, beginning on January 1, 2021 and continuing through January 1, 2030, in an amount equal to the lesser of (1) 5% of the total number of shares of the Company's common stock outstanding on December 31 of the immediately preceding year, or (2) a lesser number of shares determined by the Board no later than December 31 of the immediately preceding year.

In 2022, the Board approved and adopted the Company's 2022 Inducement Plan (the "2022 Inducement Plan"). Under the 2022 Inducement Plan, initially 2,000,000 shares of common stock were reserved for issuance. The 2022 Inducement Plan permits the grant of options, restricted stock awards, stock appreciation rights, restricted stock unit awards, performance awards, and other awards.

The exercise price for each option and stock appreciation right shall be established at the discretion of the Board, provided that the exercise price of a stock option will not be less than 100% of the fair market value of the Company's common stock on the date of grant. Specific vesting for stock options and stock appreciation rights is service related and determined in each award agreement, where stock options and stock appreciation rights are fully vested at the grant date or follow a graded vesting schedule. Stock options and stock appreciation rights granted under the plans generally expire ten years after the date of grant.

Stock Option Valuation

The fair value of stock option grants is estimated using the Black-Scholes option-pricing model. The Company lacks company-specific historical and implied volatility information. Therefore, it estimated its expected stock volatility based on the historical volatility of a publicly traded set of peer companies in addition to its own historical volatility. For options with service-based vesting conditions, the expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to nonemployees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is 0% since the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The assumptions that the Company used to determine the estimated grant-date fair value of stock options granted to employees and directors under the 2020 Plan and the 2022 Inducement Plan were as follows, presented as a weighted average:

	June 30, 2024	June 30, 2023
Risk-free interest rate	3.93%	3.48%
Expected term (in years)	6.03	6.08
Expected volatility	85.24%	87.22%
Expected dividend yield	—	—

Stock Option Activity

The following table summarizes the stock option activity under the 2014 Plan, the 2020 Plan and the 2022 Inducement Plan:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2023	8,670,742	$ 8.52	7.60	$ 61,749
Granted	3,071,250	14.56	—	—
Exercised (1)	(344,128)	3.86	—	—
Forfeited	(180,013)	16.67	—	—
Outstanding as of June 30, 2024	11,217,851	$ 10.19	7.91	$ 37,104
Options vested and exercisable as of June 30, 2024	5,565,712	$ 9.39	6.86	$ 24,380
Options expected to vest as of June 30, 2024	5,652,139	$ 10.97	8.93	$ 12,724

(1)Exercised amount includes shares returned for taxes withheld for exercise and net transactions.

Restricted Stock Awards

The following table summarizes the restricted stock activity under the 2014 Plan during the six months ended June 30, 2024:

	Number of Shares	Grant Date Fair Value
Unvested restricted stock as of December 31, 2023	92,659	$ 2.40
Granted	—	
Vested	(92,659)	2.40
Forfeited	—	
Unvested restricted stock as of June 30, 2024	—	$ —

Performance-Based Restricted Stock Unit Awards

In November 2022, the Company granted to certain employees 710,000 shares of performance-based restricted stock unit awards (the "PSUs") under the 2020 Plan as consideration for services subject to performance conditions with a fair value based on the closing price of the underlying common stock on the date of grant. Pursuant to the terms of the PSUs, 65% of each PSU vests upon certification by the Compensation Committee of the Company of achieving a pre-determined performance goal by June 30, 2024, and, 35% of each PSU vests upon certification by the Compensation Committee of the Company of achieving a pre-determined performance goal by June 30, 2024. In June 2024, pursuant to the terms of the PSUs, the Compensation Committee of the Company approved an extension of the achievement of the performance goal related to the 65% tranche of the PSUs from June 30, 2024 to December 31, 2024.

Expense recognition for PSUs commences when it is determined that attainment of the performance goal is met. During the three and six months ended June 30, 2024, no performance goal was met, and therefore, no related stock-based compensation expense was recorded.

The following table summarizes the performance-based restricted stock activity under the 2020 plan during the six months ended June 30, 2024:

	Number of Shares	Grant Date Fair Value
Outstanding as of December 31, 2023	403,000	$ 3.38
Granted	—	
Vested	—	
Forfeited	—	
Outstanding as of June 30, 2024	403,000	$ 3.38

2020 Employee Stock Purchase Plan

In 2020, the Board and the Company's stockholders approved and adopted the ESPP. The ESPP permits eligible employees who elect to participate in an offering under the ESPP to have up to 15% of their eligible earnings withheld, subject to certain limitations, to purchase shares of common stock pursuant to the ESPP. The price of the common stock purchased under the ESPP is equal to the lesser of (i) 85% of the fair market value of a share of the Company's common stock on the first day of an offering; or (ii) 85% of the fair market value of a share of the Company's common stock on the date of purchase. Each offering period is not to exceed 27 months and will include one or more purchase periods (each a "Purchase Period") as approved by the Board in the offering. A total of 430,416 shares of common stock were initially reserved for issuance pursuant to the ESPP. Subsequently, the number of shares of the Company's common stock reserved for issuance under the ESPP automatically increases on January 1 of each year for a period of up to ten years, commencing on January 1, 2021 and continuing through January 1, 2030, in amount equal to the lesser of (i) 1% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year, (ii) 860,832 shares of common stock, or (iii) a lesser number of shares determined by the Board no later than December 31 of the preceding calendar year.

The ESPP is a compensatory plan as defined by the authoritative guidance for stock-based compensation. The Company uses the Black-Scholes option-pricing model to estimate the fair value of stock offered under the ESPP. Stock-based compensation expense related to the ESPP was $0.2 million and $0.4 million for the three and six months ended June 30, 2024, respectively.

Stock-Based Compensation Expense

Stock-based compensation expense related to awards granted under the 2014 Plan, the 2020 Plan, the ESPP and the 2022 Inducement Plan was classified in the condensed consolidated statements of operations and comprehensive loss as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development	$ 4,233	$ 2,969	$ 7,645	$ 6,057
General and administrative	1,491	1,201	2,988	2,743
Total	$ 5,724	$ 4,170	$ 10,633	$ 8,800

8.Net Loss Per Common Share

Net Loss Per Common Share

Basic and diluted net loss per common share was calculated as follows (in thousands, except share and per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Numerator:				
Net loss	$ (30,382)	$ (20,095)	$ (61,352)	$ (48,381)
Denominator:				
Weighted average shares used to compute net loss per share, basic and diluted	56,282,402	40,720,294	55,928,363	40,470,041
Net loss per share, basic and diluted	$ (0.54)	$ (0.49)	$ (1.10)	$ (1.20)

The potentially dilutive shares that were excluded from the calculation of diluted net loss per share because their effect would have been anti-dilutive for the periods presented are as follows:

	Six Months Ended June 30,	
	2024	2023
Unvested restricted stock awards	—	197,274
Unvested performance-based restricted stock unit awards	403,000	710,000
Options to purchase common stock	11,217,851	9,276,718
Employee stock purchase plan contingently issuable	—	22,749
	11,620,851	10,206,741

9.Lease

The Company leases certain of its facilities under non-cancellable operating leases expiring at various dates through 2026.

On December 15, 2020, the Company entered into a lease agreement with Tennieh LLC to lease approximately 9,800 square feet of office and lab space in San Francisco, California (the “Laboratory Lease Agreement”). The Laboratory Lease Agreement is for a period of five years commencing approximately February 1, 2021 and ending January 31, 2026. According to the terms of the Laboratory Lease Agreement, the Company paid a $0.4 million security deposit and is required to pay monthly rent and common area charges.

On August 17, 2023, the Company entered into a sublease agreement with Dropbox, Inc. to sublease approximately 6,713 square feet of office space in San Francisco, California (the “Dropbox Sublease Agreement”). The Dropbox Sublease Agreement is for a period of two years commencing on September 5, 2023 and ending December 31, 2025. According to the terms of the Dropbox Sublease Agreement, the Company paid a $0.1 million security deposit and is required to pay monthly rent and common area charges.

The sublease was accounted for under Topic 842 and the Company recorded ROU asset and lease liability of $0.2 million and $0.2 million, respectively, in the accompanying condensed consolidated financial statements.

On August 23, 2023, the Company entered into a lease agreement with The Cambridge Redevelopment Authority to lease approximately 4,020 square feet of office space in Cambridge, Massachusetts (the "Cambridge Lease Agreement"). The Cambridge Lease Agreement is for a period of three years commencing on September 15, 2023 and ending September 14, 2026. According to the terms of the Cambridge Lease Agreement, the Company paid a less than $0.1 million security deposit and is required to pay monthly rent and common area charges. The lease was accounted for under Topic 842 and the Company recorded ROU asset and lease liability of $0.7 million and $0.7 million, respectively, in the accompanying condensed consolidated financial statements.

The following table summarizes total lease expense during the three and six months ended June 30, 2024 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Straight-line operating lease expense	$ 287	$ 326	$ 575	$ 653
Short-term lease expense	—	53	—	106
Variable lease expense	80	10	169	20
Total operating lease expense	$ 367	$ 389	$ 744	$ 779

The following table summarizes supplemental cash flow information during the three and six months ended June 30, 2024 and 2023 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Cash paid for amounts included measurement of lease liabilities:				
Operating cash flows from operating leases	$ 293	$ 327	$ 553	$ 653

The following table summarizes the Company's future minimum lease payments and reconciliation of lease liabilities as of June 30, 2024 (in thousands):

Years Ending December 31,	
2024 (from July 2024)	$ 610
2025	1,245
2026	263
Total future minimum lease payments	2,118
Less: Interest	(156)
Total lease liabilities at present value	1,962
Lease liabilities, current	1,103
Lease liabilities, non-current	$ 859

The following table summarizes lease term and discount rate as of June 30, 2024:

	June 30,	
	2024	2023
Weighted-average remaining lease term (years)	1.75	2.43
Weighted-average discount rate	9.00%	8.69%

10.Commitments and Contingencies

Loan Agreement

On September 5, 2023, the Company entered into the Original Loan Agreement. The Original Loan Agreement provided for a four-year senior secured credit facility in an aggregate principal amount of up to $50.0 million (the “Original Credit Facility”). On June 28, 2024, the Company entered into the Amendment which amends the Original Loan Agreement in order to, among other things, (i) increase the aggregate principal amount of the Original Credit Facility from up to $50.0 million to up to $100.0 million (the "Credit Facility"), of which $25.0 million is currently available, an additional $25.0 million will become available upon the Company achieving certain milestones related to execution of a first-line pivotal Phase 3 clinical trial of palazestrant in combination with ribociclib, and an additional $50.0 million which may be made available upon approval of the Bank in its discretion, and (ii) extend the maturity date to July 1, 2028 (the "Maturity Date"). As of June 30, 2024, the Company had not drawn down funds under the Credit Facility.

The obligations under the Loan Agreement are secured by substantially all of the assets of the Company, subject to limited exceptions.

During the term of the Credit Facility, interest will accrue on any outstanding balance due under the Credit Facility at a floating rate per annum equal to the higher of (i) 8.0% and (ii) the prime rate. During an event of default, any outstanding amount under the Credit Facility will bear interest at a rate of 3.0% in excess of the otherwise applicable rate of interest. The Company will pay certain fees with respect to the Credit Facility, including a prepayment fee on any amount advanced under the Credit Facility to the extent paid prior to the Maturity Date, a final payment fee on the amount advanced under the Credit Facility, and an unused commitment fee of 1.5% on the portion of Credit Facility that remains undrawn as of June 30, 2025, as well as certain other fees and expenses of the Bank.

The Loan Agreement contains customary events of default, including, but not limited to, nonpayment of principal, interest, fees or other amounts; material inaccuracy of a representation or warranty; failure to perform or observe covenants; cross-defaults with certain other indebtedness; bankruptcy and insolvency events; material monetary judgment defaults; material adverse change occurs; delisting; and a material impairment in the Bank’s security interest. Upon the occurrence of an event of default (subject, in certain cases, to notice and grace periods), obligations under the Loan Agreement may be accelerated.

The Loan Agreement also contains a number of customary representations, warranties and covenants that, among other things, limit the ability of the Company to (subject to certain qualifications and exceptions): create liens and encumbrances; incur additional indebtedness; merge, dissolve, liquidate or consolidate; make acquisitions, investments, advances or loans; dispose of or transfer assets; pay dividends or make other payments in respect of its capital stock; amend certain material documents; redeem or repurchase certain debt; make payments on subordinated debt; and engage in certain transactions with affiliates.

Clinical Collaboration and Supply Agreement

On July 22, 2020, the Company entered into a non-exclusive clinical collaboration and supply agreement with Novartis Institutes for BioMedical Research, Inc. (“Novartis”). On January 13, 2022, the Company entered into the amended and restated clinical collaboration and supply agreement with Novartis, and on October 9, 2023, the Company and Novartis entered into the amendment no. 1 (the “Novartis Amendment 1”) to amended and restated clinical collaboration and supply agreement, and on March 22, 2024, the Company and Novartis entered into the amendment no. 2 (the “Novartis Amendment 2”) to amended and restated clinical collaboration and supply agreement (as amended, the “Novartis Agreement”). The collaboration is focused on the evaluation of the safety, tolerability and efficacy of palazestrant in combination with Novartis’ proprietary CDK4/6 inhibitor Kisqali® (ribociclib) and/or Novartis’ proprietary phosphatidylinositol 3-kinase (“PI3Ka”) Inhibitor Piqray® (alpelisib) (collectively the “Novartis Study Drugs”) as part of the Company’s Phase 1b/2 clinical study of palazestrant in patients with metastatic estrogen receptor-positive breast cancer. The Novartis Amendment 1, among other things, expanded our clinical collaboration with Novartis, increasing the size of the ongoing Phase 1/2 clinical study testing palazestrant in combination with ribociclib to approximately 60 patients and Novartis

Amendment 2 increased the size of the ongoing Phase 1/2 clinical study testing palazestrant in combination with ribociclib by an additional 15 patients exploring 90 mg of palazestrant in combination with 600 mg of ribociclib. The Company will be responsible for the conduct of the clinical trials for the combined therapies in accordance with a mutually agreed development plan. As part of the collaboration, the parties granted to each other a non-exclusive, royalty-free license under certain of the parties' respective background patent rights and other technology to use the parties' respective study drugs in research and development, solely to the extent reasonably needed for the other party's activities in the collaboration. All inventions and data developed in the performance of the clinical trials for the combined therapies (other than those specific to each component study drug), will be jointly owned by the parties.

The Company is responsible for manufacturing, packaging and labeling palazestrant, and for packaging and labeling all drugs used in the clinical trials for the combined therapies (other than the Novartis Study Drugs). Novartis is responsible for manufacturing and delivering to the Company the Novartis Study Drugs in such quantities as reasonably needed for the clinical trials for the combined therapies. In accordance with an agreed budget, subject to certain thresholds, Novartis will reimburse the Company for a majority of the direct outside costs that the Company incurs related to conducting the activities under the agreed development plan in conducting the clinical trials for the combined therapies.

The Novartis Agreement will terminate upon completion of all activities outlined in the development plan and the relevant protocols. Either party may terminate the Novartis Agreement for the uncured material breach or insolvency of the other party, if it reasonably deems it necessary in order to protect the safety, health or welfare of subjects enrolled in the clinical trials for the combined therapies due to the existence of a material safety issue, or in certain circumstances for an unresolved clinical hold with respect to either the Novartis Study Drugs or palazestrant. In addition, Novartis may terminate the Novartis Agreement if certain disputes between the parties are not resolved after following the applicable dispute resolution procedures, and the Company may terminate the Novartis Agreement in the event the Company terminates all clinical trials of the combined therapies other than due to a material safety issue or upon a clinical hold.

Costs associated with research activities performed under the agreement are included in research and development expenses in the accompanying condensed consolidated financial statements, with any reimbursable costs from Novartis reflected as a reduction of such expenses. As of December 31, 2023, the Company had incurred the full agreed-upon reimbursement amount. As of June 30, 2024, there was no outstanding balance from the receivable due from Novartis.

Clinical Trial Agreement

In November 2020, the Company entered into a non-exclusive clinical trial agreement with Pfizer Inc. ("Pfizer") (the "Pfizer Agreement"), to evaluate the safety and tolerability of palazestrant in combination with Pfizer's proprietary CDK4/6 inhibitor IBRANCE® (palbociclib) in patients with recurrent, locally advanced or metastatic ER+, HER2 breast cancer in a clinical trial. Under the terms of the non-exclusive agreement, the Company will be responsible for conducting the clinical trial for the combined therapies and Pfizer is responsible for supplying IBRANCE® to the Company at no cost to the Company. As part of the collaboration, the parties granted to each other a non-exclusive, royalty-free license under certain of the parties' respective patent rights in the combination of IBRANCE® and palazestrant to use the parties' respective study drugs in research and development, solely to the extent reasonably needed for the other party's activities in the collaboration. All inventions and data developed in the performance of the clinical trials for the combined therapies (other than those specific to each component study drug), will be jointly owned by the parties.

The Company is responsible for manufacturing, packaging and labeling palazestrant, and for packaging and labeling all drugs used in the clinical trials for the combined therapies (other than IBRANCE®). Pfizer is responsible for manufacturing and delivering to us IBRANCE® in such quantities as reasonably needed for the clinical trials for the combined therapies.

The Pfizer Agreement will terminate upon completion of all activities outlined in the study plan and the relevant protocols. Either party may terminate the Pfizer Agreement for the uncured material breach or insolvency of the other party, if it reasonably deems it necessary in order to protect the safety, health or welfare of subjects enrolled in the clinical trials for the combined therapies due to the existence of a material safety issue, or in

certain circumstances for an unresolved clinical hold with respect to either the IBRANCE® or palazestrant. In addition, either party may terminate the Pfizer Agreement if certain disputes between the parties are not resolved after following the applicable dispute resolution procedures or if either party determines to discontinue clinical development for medical, scientific, legal or other reasons.

The Pfizer Agreement does not grant any right of first negotiation to participate in future clinical trials, and each of the parties retains all rights and ability to evaluate their respective compounds. Costs incurred in connection to the Pfizer Agreement are included in the research and development expense in the accompanying condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2024, and 2023.

License Agreement

In June 2022, the Company entered into an exclusive global license agreement with Aurigene Discovery Technologies Limited ("Aurigene") to research, develop and commercialize novel small molecule inhibitors of an undisclosed oncology target ("the Aurigene Agreement").

Under the terms of the Aurigene Agreement, Aurigene will provide to the Company an exclusive license to its portfolio of novel small molecule inhibitors of the target. Financial terms of the Aurigene Agreement include a $8.0 million upfront payment for rights to a pre-existing Aurigene program and potential future milestone payments of up to $60.0 million in clinical development and regulatory milestones, and up to $370.0 million in commercial milestones. Aurigene is also eligible to receive mid-single digits to the low double digits royalties as percentages of product sales, if any. During the research term, the Company will contribute funding to Aurigene to facilitate Aurigene's ongoing discovery efforts. The Company and Aurigene will jointly direct further preclinical work and, if successful, the Company will lead clinical development as well as regulatory and commercial activities. The Company and Aurigene jointly own collaboration compounds and rights to any inventions made during the research term.

The term of the Aurigene Agreement will continue until the expiration of the last-to-expire of all payment obligations with respect to all licensed products thereunder, unless terminated earlier in accordance with the terms of the Aurigene Agreement. The Aurigene Agreement may be terminated (a) by the Company for convenience, in its sole discretion, upon prior written notice to Aurigene, (b) by either the Company or Aurigene in connection with the other party's uncured material breach or (c) by either the Company or Aurigene in connection with the insolvency of the other party.

The $8.0 million upfront payment was incurred in June 2022 and recorded as research and development expense in the accompanying condensed consolidated statements of operations and comprehensive loss. Costs incurred and milestones payments due to Aurigene prior to regulatory approval are recognized as research and development expenses in the period incurred. Payments due to Aurigene upon or subsequent to regulatory approval will be accrued as a provision to cost of sales in the period when achievement of respective milestone target is probable. The $5.0 million milestone payment related to initiation of the first IND-enabling safety study was incurred and recorded as research and development expenses in the accompanying condensed consolidated statement of operations and comprehensive loss during the three months ended March 31, 2024. There was no milestone met during the three months ended June 30, 2024.

Management Services Agreements

The Company conducts research and development programs internally and through third parties that include, among others, arrangements with vendors, consultants, CMOs, and CROs. The Company has contractual arrangements in the normal course of business with these parties, however, the contracts with these parties are cancelable generally on reasonable notice within one year and the Company's obligations under these contracts are primarily based on services performed through termination dates plus certain cancelation charges, if any, as defined in each of the respective agreements. In addition, these agreements may, from time to time, be subjected to amendments as a result of any change orders executed by the parties. As of June 30, 2024, the Company did not have material contractual commitments with respect to these arrangements.

Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business. The Company accrues a liability for such matters when it is probable that future expenditures will be made, and such expenditures can be reasonably estimated. For all periods presented, the Company was not a party to any pending material litigation or other material legal proceedings.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its Board and executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. As of June 30, 2024, the Company had not incurred any material costs as a result of such indemnifications.

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

You should read the following discussion and analysis of our financial condition and results of operations together with the unaudited condensed consolidated financial statements and related notes that are included elsewhere in this Quarterly Report on Form 10-Q and the audited financial statements and related notes that are included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the U.S. Securities and Exchange Commission, or the SEC, on March 11, 2024, or our Annual Report on Form 10-K.

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Forward-looking statements are identified by words such as "believe," "will," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "could," "potentially" or the negative of these terms or similar expressions. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this report in Part II, Item 1A — "Risk Factors," and elsewhere in this report. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments. We caution investors that our business and financial performance are subject to substantial risks and uncertainties. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject, and these statements are based on information available to us as of the date of this Quarterly Report on Form 10-Q. While we believe that such information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into or review of all relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely on these statements.

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of next generation targeted therapies for women's cancers. We are advancing our pipeline of novel therapies by leveraging our deep understanding of endocrine-driven cancers, nuclear receptors, and mechanisms of acquired resistance. Our lead product candidate, palazestrant (OP-1250), is a novel, orally-available small molecule with dual activity as both a complete estrogen receptor, or ER, antagonist, or CERAN, and selective ER degrader, or SERD, currently being investigated in patients with recurrent, locally advanced or metastatic ER-positive, or ER+, human epidermal growth factor receptor 2-negative, or HER2-, breast cancer. In preclinical models, palazestrant binds and completely blocks ER-driven transcriptional activity in both wild-type and mutant forms of metastatic ER+ breast cancer including activity in central nervous system, or CNS, metastases models. In clinical studies across more than 300 patients, palazestrant has demonstrated strong anti-tumor activity, attractive pharmacokinetics and prolonged drug exposure, favorable tolerability, and combinability with CDK4/6 inhibitors with no significant drug-drug interaction. Palazestrant is being evaluated as a single agent in an ongoing Phase 3 clinical trial, OPERA-01, and in Phase 1/2 combination studies with a CDK4/6 inhibitor (palbociclib or ribociclib), a phosphatidylinositol 3 kinase alpha, or PI3Ka, inhibitor (alpelisib), and an anticipated Phase 1b/2 combination study with an mTOR inhibitor (everolimus).

We reported positive Phase 2 clinical results for palazestrant as a monotherapy in October 2023 at the European Society for Medical Oncology, or ESMO, Congress 2023, which demonstrated compelling progression-free survival, or PFS, a favorable tolerability profile and attractive pharmacokinetics in a heavily pretreated patient population. These results validated the potential opportunity for palazestrant as a monotherapy agent in later lines of treatment for metastatic breast cancer, and in November 2023 we initiated

OPERA-01, our pivotal Phase 3 second-, third-line monotherapy clinical trial. We anticipate the top-line results from the OPERA-01 trial in 2026.

We are investigating palazestrant in combination with CDK4/6 inhibitors, palbociclib and ribociclib, and a PI3Ka inhibitor, alpelisib. We presented interim results from the Phase 2 portion of the palazestrant-ribociclib combination clinical study at the ESMO Breast Cancer Annual Congress 2024 in May 2024 in Berlin, Germany. As of the data cut-off date of March 13, 2024, the combination of the palazestrant recommended Phase 2 dose, or RP2D, of 120 mg in combination with the full U.S. Food and Drug Administration, or FDA-approved label dose of 600 mg of ribociclib was well tolerated with no new safety signals or enhancement of toxicity and palazestrant did not affect ribociclib drug exposure while ribociclib had no clinically meaningful effect on palazestrant drug exposure. Furthermore, the results for the maturing dataset showed anti-tumor activity and prolonged disease stabilization, and a clinical benefit rate, or CBR, of 85% across 13 CBR-eligible patients. We expect the data from the Phase 2 palazestrant-ribociclib combination clinical study will enable us to prepare to initiate a pivotal Phase 3 first-line clinical trial of palazestrant in combination with ribociclib. We anticipate providing updated results from the Phase 2 clinical study at a future medical meeting. We also reported interim results of our ongoing Phase 2 dose expansion clinical studies of palazestrant in combination with palbociclib at the 2023 San Antonio Breast Cancer Symposium in December 2023. The interim results demonstrated no significant drug-drug interaction, no dose-limiting toxicities, and a tolerability profile consistent with the FDA-approved labels of palbociclib plus an endocrine therapy. The study is being conducted at the RP2D for palazestrant combined with the full FDA-approved label dose of palbociclib 125 mg.

In October 2023, we announced the expansion of our clinical collaboration with Novartis Institutes for BioMedical Research, Inc., or Novartis, increasing the size of the ongoing Phase 1/2 clinical study testing palazestrant in combination with ribociclib to approximately 60 patients, and in March 2024, we further increased the size of the ongoing Phase 1/2 clinical study testing palazestrant in combination with ribociclib by an additional 15 patients exploring 90 mg of palazestrant in combination with 600 mg of ribociclib. We also plan to initiate evaluation of palazestrant in combination with an mTOR inhibitor, everolimus, in a Phase 1b/2 clinical study, anticipated in the third quarter of 2024.

In July 2022, we were granted Fast Track designation from the FDA for palazestrant for patients with ER+/HER2- metastatic breast cancer that has progressed following one or more lines of endocrine therapy with at least one line given in combination with a CDK4/6 inhibitor.

In addition, in October 2023 we presented new preclinical data regarding the discovery of novel compounds targeting KAT6, an epigenetic target that is dysregulated in breast and other cancers. In January 2024, we nominated a development candidate for this program, OP-3136. We have completed Investigational New Drug, or IND, enabling studies for OP-3136, and we anticipate providing additional pre-clinical data for OP-3136 in the fourth quarter of 2024. We expect to file an IND application with the FDA in late 2024 and advance into clinical development. In a non-clinical xenograft model, OP-3136 caused dose-dependent tumor growth inhibition and tumor regression comparable to or better than a positive-control patented KAT6 inhibitor and demonstrated synergy in combination with CDK4/6 inhibitors or palazestrant. We are advancing the development of this program in collaboration with Aurigene Oncology, or Aurigene.

Since our inception, we have devoted substantially all of our resources to organizing and staffing our company, research and development activities, business planning, raising capital, establishing and maintaining our intellectual property portfolio, conducting non-clinical studies and clinical trials and providing general and administrative support for these operations.

We do not have any product candidates approved for commercial sale, and we have not generated any revenue from product sales. Our ability to generate product revenue sufficient to achieve profitability, if ever, will depend on the successful development and eventual commercialization of one or more of our product candidates which we expect, if it ever occurs, will take a number of years. We also do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for non-clinical and clinical testing, as well as for commercial manufacturing if any of our product candidates obtain marketing approval. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment and personnel while also enabling us to focus our expertise and resources on the development of our product candidates.

We have incurred significant operating losses since the commencement of our operations. Our net losses were $30.4 million and $20.1 million for the three months ended June 30, 2024 and 2023, respectively, and $61.4 million and $48.4 million for the six months ended June 30, 2024 and 2023, respectively. We expect to incur significant and increasing losses for the foreseeable future as we continue to advance our product candidates, make potential milestone payments to our licensors, and as we continue to operate as a public company. Our net losses may fluctuate significantly from period to period, depending on the timing of expenditures on our research and development activities. As of June 30, 2024, we had an accumulated deficit of $367.0 million. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures and general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and other current liabilities.

We expect to continue to incur net operating losses for at least the next several years, and we expect our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. We expect our expenses and capital requirements will increase significantly in connection with our ongoing activities as we:

- continue our ongoing and planned research and development of our lead product candidate, palazestrant, for the treatment of ER+ positive breast cancer;
- initiate non-clinical studies and clinical trials for OP-3136 and any additional product candidates that we may pursue in the future;
- seek to discover and develop additional product candidates and further expand our clinical product pipeline;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- continue to scale up external manufacturing capacity with the aim of securing sufficient quantities to meet our capacity requirements for clinical trials and potential commercialization;
- establish a sales, marketing and distribution infrastructure to commercialize any approved product candidates and related additional commercial manufacturing costs;
- develop, maintain, expand, protect and enforce our intellectual property portfolio, including patents, trade secrets and know how;
- acquire or in-license other product candidates and technologies;
- attract, hire and retain additional clinical, scientific, quality control, and manufacturing management and administrative personnel;
- add clinical, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts;

- expand our operations in the United States and to other geographies; and

- incur additional legal, accounting, investor relations and other expenses associated with operating as a public company.

Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials, potential milestone payments to our licensors, and our expenditures on other research and development activities.

We will require substantial additional funding to develop our product candidates and support our continuing operations beyond our current operating plans. Until such time that we can generate significant revenue from product sales or other sources, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, which could include income from collaborations, strategic partnerships or marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. We may be unable to raise additional funds or to enter into such agreements or arrangements on favorable terms, or at all. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and volatility in, the credit and financial markets in the United States and worldwide resulting from geopolitical and macroeconomic conditions. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations or financial condition, including requiring us to have to delay, reduce or eliminate our product development or future commercialization efforts. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our development efforts. We cannot provide assurance that we will ever be profitable or generate positive cash flow from operating activities.

Global economic and business activities continue to face widespread geopolitical and macroeconomic uncertainties, including labor shortages, inflation rates and the responses by central banking authorities to control such inflation, monetary supply shifts, and related financial market risks and instability, recession risks, as well as potential disruptions from the Russia-Ukraine conflict and armed conflict between Israel and groups based in surrounding regions, all of which have resulted in volatility in the U.S. and global financial markets, and disruptions to trade, commerce, pricing stability, credit availability and supply chain continuity globally. The extent of the impact of these factors on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected time frame, will depend on future developments, which are uncertain and cannot be predicted. Any continued or renewed disruption resulting from these factors could negatively impact our business. We continue to monitor the impact of these geopolitical and macroeconomic factors on our results of operations, financial condition and cash flows.

Components of our results of operations

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products for the foreseeable future.

Operating expenses

Research and development

Research and development expenses account for a significant portion of our operating expenses and consist primarily of external and internal expenses incurred in connection with the discovery and development of our product candidates. To date, our research and development expenses have related primarily to discovery efforts and non-clinical and clinical development of our lead product candidate, palazestrant, as well as OP-3136. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

External expenses include:

- expenses incurred in connection with the discovery and non-clinical development of our product candidates, including under agreements with third parties, such as consultants and contract research organizations, or CROs;
- costs of manufacturing products for use in our non-clinical studies and clinical trials, including payments to contract manufacturing organizations, or CMOs, and consultants;
- costs of funding research performed by third parties;
- costs of purchasing lab supplies and non-capital equipment used in designing, developing and manufacturing non-clinical study and clinical trial materials;
- costs associated with consultants for chemistry, manufacturing and controls development, regulatory, statistics and other services;
- expenses related to regulatory activities, including filing fees paid to regulatory agencies; and
- facility costs including rent, depreciation and maintenance expenses.

Internal expenses include employee and personnel-related costs and expenses, including salaries, benefits and stock-based compensation expense for employees and personnel engaged in research and development functions.

We expense research and development expenses in the periods in which they are incurred. Costs for certain activities, such as manufacturing and non-clinical studies and clinical trials, are generally recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and collaborators.

We typically use our employee, consultant and infrastructure resources across our development programs. We track outsourced development costs by product candidate or non-clinical program, but we do not allocate personnel costs, other internal costs or external consultant costs to specific product candidates or non-clinical programs.

While our research and development expenses may fluctuate from period to period, we generally expect our research and development expenses to increase substantially in absolute dollars for the foreseeable future as we advance palazestrant, OP-3136 or any other future product candidates we may develop into and through non-clinical studies and clinical trials and pursue regulatory approval of our product candidates. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for palazestrant, OP-3136 or any other future product candidates we may develop may be affected by a variety of factors including but not limited to: the safety and efficacy of our product candidates, early clinical data, investment in our clinical program, the ability of collaborators to successfully develop our licensed product candidates, competition, manufacturing capability and commercial viability. We may never succeed in achieving regulatory approval for our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of palazestrant, OP-3136 or any other future product candidates we may develop. Clinical and non-clinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future non-clinical studies and clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. In addition, we cannot forecast whether palazestrant, OP-3136 or any other future product candidates we may develop may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. We are also unable to predict when, if ever, we will generate revenue from our product candidates to offset these expenses. Our expenditures on current and future non-clinical and clinical

development programs are subject to numerous uncertainties in timing and cost to completion. The duration, costs and timing of non-clinical studies and clinical trials and development of our product candidates will depend on a variety of factors, including:

- the timing and progress of non-clinical and clinical development activities;
- the number and scope of non-clinical and clinical programs we decide to pursue;
- our ability to maintain our current research and development programs and to establish new ones;
- establishing an appropriate safety profile with investigational new drug-enabling toxicology studies;
- successful patient enrollment in, and the initiation and completion of, clinical trials;
- the successful completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- receipt of regulatory approvals from applicable regulatory authorities;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- our ability to establish licensing or collaboration arrangements;
- the performance of our future collaborators, if any;
- development and timely delivery of commercial-grade product formulations that can be used in our planned clinical trials and for commercial launch;
- commercializing the product candidates, if approved, whether alone or in collaboration with others;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- maintaining continued acceptable safety profiles of our products following approval; and
- obtaining and retaining key research and development personnel.

Any changes in the outcome of any of these factors could significantly impact the costs, timing and viability associated with the development of our product candidates.

General and administrative

General and administrative expenses consist primarily of personnel expenses, including salaries, benefits and stock-based compensation expense, for personnel in executive, finance, accounting, business development, legal, human resources, information technology, or IT, and administrative functions. General and administrative expenses also include costs not otherwise included in research and development expenses, including corporate facility costs, depreciation and other expenses, which include direct or allocated expenses for rent and maintenance of facilities and insurance, and professional fees for legal, patent and consulting services.

While our general and administrative expenses may fluctuate from period to period, we generally expect that our general and administrative expenses will increase in the foreseeable future as we increase our headcount

to support the continued research and development of our programs and the growth of our business. We also anticipate incurring additional expenses associated with operating as a public company, including increased expenses related to the building and improving of our IT infrastructure, including cyber security monitoring, legal, other regulatory and compliance, director and officer insurance, investor and public relations and tax-related services associated with maintaining compliance with the rules and regulations of the SEC and standards applicable to companies listed on a national securities exchange, additional insurance expenses, investor relations activities and other administrative and professional services.

Total other income

Total other income consists of interest income and other income. Interest income primarily consists of interest income on our cash equivalents and marketable securities. Other income primarily consists of unrealized foreign currency remeasurement gain (loss) and miscellaneous income (expense) not related to operating activities.

Results of operations

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

The following table summarizes our results of operations for the three months ended June 30, 2024 and 2023:

	Three Months Ended June 30,		
	2024	2023	$ Change
	(in thousands)		
Operating expenses:			
Research and development	$ 29,109	$ 17,989	$ 11,120
General and administrative	4,421	3,612	809
Total operating expenses	33,530	21,601	11,929
Loss from operations	(33,530)	(21,601)	(11,929)
Other income:			
Interest income	3,108	1,550	1,558
Other income (expense)	40	(44)	84
Total other income	3,148	1,506	1,642
Net loss	$ (30,382)	$ (20,095)	$ (10,287)

Research and development expenses

The following table summarizes our research and development expenses by functional area for the three months ended June 30, 2024 and 2023:

	Three Months Ended June 30,		
	2024	2023	$ Change
	(in thousands)		
CROs, CMOs and other clinical development related third-party vendor expenses	$ 12,238	$ 6,388	$ 5,850
Compensation and related benefits	6,693	4,885	1,808
Other research and development expenses	5,945	3,747	2,198
Stock-based compensation	4,233	2,969	1,264
Total research and development expenses	$ 29,109	$ 17,989	$ 11,120

Research and development expenses for the three months ended June 30, 2024 were $29.1 million, compared to $18.0 million for the three months ended June 30, 2023. The increase of $11.1 million was primarily due to (i) increased spending on clinical operations and development-related activities as we continue to advance palazestrant into late-stage clinical trials, (ii) other research and development activities associated with the advancement of our KAT6 inhibitor program, and (iii) personnel-related costs, including an increase in non-cash stock-based compensation expense of $1.3 million.

General and administrative expenses

General and administrative expenses for the three months ended June 30, 2024 were $4.4 million compared to $3.6 million for the three months ended June 30, 2023. The increase of $0.8 million was primarily due to (i) increased spending on corporate-related costs, and (ii) an increase in non-cash stock-based compensation expense of $0.3 million.

Other income

Other income for the three months ended June 30, 2024 was $3.1 million, compared to $1.5 million for the three months ended June 30, 2023. The increase of $1.6 million was primarily due to an increase in interest income from our marketable securities.

Results of operations

Comparison of the six months ended June 30, 2024 and 2023

The following table summarizes our results of operations for the six months ended June 30, 2024 and 2023:

	Six Months Ended June 30,		
	2024	2023	$ Change
	(in thousands)		
Operating expenses:			
Research and development	$ 58,992	$ 40,815	$ 18,177
General and administrative	8,877	10,388	(1,511)
Total operating expenses	67,869	51,203	16,666
Loss from operations	(67,869)	(51,203)	(16,666)
Other income:			
Interest income	6,460	2,855	3,605
Other income (expense)	57	(33)	90
Total other income	6,517	2,822	3,695
Net loss	$ (61,352)	$ (48,381)	$ (12,971)

Research and development expenses

The following table summarizes our research and development expenses by functional area for the six months ended June 30, 2024 and 2023:

	Six Months Ended June 30,		
	2024	2023	$ Change
	(in thousands)		
CROs, CMOs and other clinical development related third-party vendor expenses	$ 22,960	$ 14,368	$ 8,592
Compensation and related benefits	12,645	12,367	278
Other research and development expenses	10,742	8,023	2,719
Stock-based compensation	7,645	6,057	1,588
Milestone payment made to Aurigene	5,000	—	5,000
Total research and development expenses	$ 58,992	$ 40,815	$ 18,177

Research and development expenses for the six months ended June 30, 2024 were $59.0 million, compared to $40.8 million for the six months ended June 30, 2023. The increase of $18.2 million was primarily due to (i) increased spending on clinical operations and development-related activities as we continue to advance palazestrant into late-stage clinical trials, (ii) a $5.0 million milestone payment made to Aurigene in connection with the exclusive global license agreement entered into in June 2022 between the Company and Aurigene, or the Aurigene Agreement, (iii) other research and development activities associated with the advancement of our KAT6 inhibitor program, and (iv) personnel-related costs, including an increase in non-cash stock-based compensation expense of $1.6 million.

General and administrative expenses

General and administrative expenses for the six months ended June 30, 2024 were $8.9 million compared to $10.4 million for the six months ended June 30, 2023. The decrease of $1.5 million was primarily due to (i) decreased spending on corporate- and legal-related costs, and (ii) decreased personnel-related expenses, including a $1.0 million one-time restructuring charge recorded in the first quarter of 2023. The decrease was partially offset by an increase in non-cash stock-based compensation expense of $0.3 million.

Other income

Other income for the six months ended June 30, 2024 was $6.5 million, compared to $2.8 million for the six months ended June 30, 2023. The increase of $3.7 million was primarily due to an increase in interest income from our marketable securities.

Liquidity and capital resources

Sources of liquidity

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from our operations. Our net losses were $30.4 million and $20.1 million for the three months ended June 30, 2024 and 2023, respectively. Through June 30, 2024, we had received aggregate gross proceeds of $551.3 million from sales of our common stock, convertible preferred stock and issuance of convertible promissory notes, stock option exercises, and sale of stock through the Company's 2020 Employee Stock Purchase Plan, or ESPP.

As of June 30, 2024, we had $239.1 million in cash, cash equivalents and marketable securities and accumulated deficit of $367.0 million. We had no debt outstanding as of June 30, 2024.

In September 2023, we entered into a stock purchase agreement for a private placement of 13,211,381 shares of our common stock, at a price of $9.84 per share, to selected institutional and accredited investors, or the Private Placement, resulting in gross proceeds of approximately $130.0 million. After deducting offering expenses related to the Private Placement of approximately $0.3 million, the net proceeds to us from the Private Placement were approximately $129.7 million.

On September 5, 2023, we entered into a loan and security agreement, or the Original Loan Agreement, with Silicon Valley Bank, a division of First Citizens Bank & Trust Company, or the Bank, which provided us with an aggregate principal amount of up to $50.0 million, or the Original Credit Facility. On June 28, 2024, we entered into the First Amendment to Loan and Security Agreement, or the Amendment, and the Original Loan Agreement as amended by the Amendment, the Loan Agreement, with the Bank. The Amendment amends the Original Loan Agreement in order to, among other things, (i) increase the aggregate principal amount of the Original Credit Facility from up to $50.0 million to up to $100.0 million, or the Credit Facility, of which $25.0 million is currently available, an additional $25.0 million will become available upon achieving certain milestones related to execution of a first-line pivotal Phase 3 clinical trial of palazestrant in combination with ribociclib, and an additional $50.0 million which may be made available upon approval of the Bank in its discretion, and (ii) extend the maturity date to July 1, 2028. As of June 30, 2024, we had not drawn down from the Credit Facility.

On January 5, 2024, we entered into a sales agreement, or the Sales Agreement, with Cowen and Company, LLC, or TD Cowen, as sales agent, pursuant to which we may offer and sell, from time to time, shares of our

common stock, having an aggregate offering price of up to $150.0 million, or the ATM Shares. The sales, if any, of the ATM Shares will be made by any method permitted that is deemed to be an “at-the-market”, or ATM, equity offering as defined in Rule 415(a)(4) promulgated under the Securities Act, including sales made directly on or through the Nasdaq Global Select Market. We have agreed to pay TD Cowen a commission of up to 3.0% of the aggregate gross proceeds from any ATM Shares sold by TD Cowen. During the three months ended June 30, 2024, we issued 1,225,952 shares of our common stock under the Sales Agreement at a weighted-average price of $12.14 per share for net proceeds of $14.9 million after deducting related issuance costs. During the six months ended June 30, 2024, we issued 1,772,278 shares of our common stock under the Sales Agreement at a weighted-average price of $13.19 for net proceeds of $22.8 million after deducting related issuance costs. As of June 30, 2024, approximately $126.6 million remained available for issuance under the Sales Agreement.

We expect to incur significant expenses and operating losses for the foreseeable future as we advance the clinical development of palazestrant, OP-3136 and non-clinical studies. We expect that our research and development and general and administrative costs will increase in connection with conducting additional non-clinical studies and clinical trials for our current and future research programs and product candidates, contracting with CMOs to support non-clinical studies and clinical trials, expanding our intellectual property portfolio, and providing general and administrative support for our operations. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements or other sources.

Our primary uses of cash are to fund our research and development activities, including with respect to palazestrant, OP-3136 and other non-clinical programs, business planning, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital and providing general and administrative support for these operations.

Other than as noted above, we currently have no financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years.

Future funding and material cash requirements

To date, we have not generated any revenue from product sales. We do not expect to generate any meaningful revenue unless and until we obtain regulatory approval of and commercialize any of our product candidates, and we do not know when, or if at all, that will occur. We expect our expenses to increase in connection with our ongoing activities, particularly as we initiate and conduct clinical trials of, and seek marketing approval for, palazestrant or OP-3136. In addition, if we obtain marketing approval for our product candidates, we expect to incur significant commercialization expenses related to program sales, marketing, manufacturing and distribution to the extent that such sales, marketing and distribution are not the responsibility of potential collaborators. Furthermore, we have incurred and expect to continue to incur additional costs associated with operating as a public company. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our development efforts.

We expect our cash, cash equivalents, and marketable securities as of June 30, 2024, as well as the available balance under the Credit Facility, will enable us to fund our current operating plan for at least the next 12 months from the filing date of these condensed consolidated financial statements.

Refer to Note 10 of our notes to the condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q for further information regarding our material cash requirements; other than as set forth therein, there have been no material changes outside the ordinary course of business during the three months ended June 30, 2024 to our commitments and contingencies disclosed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K.

If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of product discovery, non-clinical studies and clinical trials;

- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we enter into;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under collaboration agreements, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of securing manufacturing arrangements for commercial production; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our product candidates.

Identifying potential product candidates and conducting non-clinical studies and clinical trials is a time- consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of one or more product candidates that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, existing stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of existing stockholders. 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 dividends.

If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Cash flows

The following table shows a summary of our cash flows for each of the periods presented:

	Six Months Ended June 30,	
(in thousands)	**2024**	**2023**
Net cash used in operating activities	$ (51,051)	$ (42,507)
Net cash (used in) provided by investing activities	(25,022)	51,500
Net cash provided by financing activities	24,426	2,263
Net (decrease) increase in cash and cash equivalents	$ (51,647)	$ 11,256

Operating activities

Net cash used in operating activities during the six months ended June 30, 2024 consisted primarily of our net loss of $61.4 million and non-cash interest income on our marketable securities of $4.5 million, offset by a net increase in operating assets and liabilities of $4.0 million and non-cash charges of $10.8 million. The net loss consisted primarily of $59.0 million in research and development expenses and $8.9 million in general and administrative expenses. The non-cash charges consisted primarily of stock-based compensation expense of $10.6 million, depreciation and amortization expenses of $0.2 million, and non-cash lease expense of less than $0.1 million, net of cash payments of $0.6 million. The net increase in operating assets and liabilities was primarily due to (i) an increase of $3.2 million in accrued and other current liabilities, (ii) an increase of $1.7 million in accounts payable, and (iii) a decrease of $1.6 million in prepaid expenses and other current assets, which is primarily due to the reimbursable research and development costs received from a collaboration partner. The changes were partially offset by an increase of $2.4 million in other assets and long-term deposits.

Net cash used in operating activities in the six months ended June 30, 2023 consisted primarily of our net loss of $48.4 million and a net decrease in operating assets and liabilities of $1.1 million, partially offset by non-cash charges of $7.0 million. The net loss consisted primarily of $40.8 million in research and development expenses and $10.4 million in general and administrative expenses. The non-cash charges consisted primarily of stock-based compensation expense of $8.8 million and depreciation and amortization expenses of $0.2 million, primarily offset by non-cash interest income on our marketable securities of $2.0 million. The net decrease in operating assets and liabilities was primarily due to (i) a decrease of $2.7 million in accrued and other current liabilities and (ii) an increase of $0.1 million in other assets and long-term deposits. The changes were partially offset by (i) an increase of $1.3 million in accounts payable, which is primarily a result of timing of invoice payment, and (ii) a decrease of $0.4 million in prepaid expenses and other current assets.

Investing Activities

Net cash used in investing activities during the six months ended June 30, 2024 was predominantly due to purchases of marketable securities which were partially offset by maturities of marketable securities.

Net cash provided by investing activities during the six months ended June 30, 2023 was predominantly due to maturities of marketable securities which were offset by purchases of marketable securities.

Financing activities

Net cash provided by financing activities during the six months ended June 30, 2024 consists of $22.8 million in net proceeds from the sale of ATM Shares, $1.0 million from the exercise of stock options, and $0.7 million from the sale of our common stock under the ESPP.

Net cash provided by financing activities during the six months ended June 30, 2023 consists of $1.6 million and $0.7 million in net proceeds from the exercise of stock options and the sale of our common stock under the ESPP, respectively.

Critical accounting policies and significant judgments and estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of our condensed consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, expenses and the disclosure of our contingent liabilities in our condensed consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

During the three months ended June 30, 2024, there were no material changes to our critical accounting policies and estimates as reported in our Annual Report on Form 10-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

During the three months ended June 30, 2024, there were no material changes to our market risk disclosures reported in our Annual Report on Form 10-K.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of June 30, 2024, management, with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2024, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended June 30, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II-OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not currently a party to any material legal proceedings. Regardless of outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Item 1A. Risk Factors.

Our business involves significant risks, some of which are described below. You should carefully consider the following risks, as well as the other information in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events or developments described below could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and the market price of our common stock.

RISK FACTOR SUMMARY

Investing in our common stock involves numerous risks, including the risks described in "Part II, Item 1A. Risk Factors" of this Quarterly Report on Form 10-Q. Below are some of these risks, any one of which could materially adversely affect our business, financial condition, results of operations, and prospects.

- We have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.

- We require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs of our product candidates or future commercialization efforts.

- We have incurred net losses since inception, and we expect to continue to incur net losses for the foreseeable future. In addition, we may be unable to continue as a going concern over the long term.

- We are substantially dependent on the success of our lead product candidate, palazestrant, which is currently in clinical development. If we are unable to complete development of, obtain regulatory approval for and commercialize palazestrant in one or more indications and in a timely manner, our business, financial condition, results of operations and prospects will be significantly harmed.

- Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development. We have never completed a pivotal clinical trial or submitted a New Drug Application, or NDA, to the FDA or similar drug approval filings to comparable foreign authorities. If we are ultimately unable to obtain regulatory approval for palazestrant or OP-3136, we will be unable to generate product revenue and our business, financial condition, results of operations and prospects will be significantly harmed.

- Even if approved, palazestrant or OP-3136 may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

•We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than palazestrant, OP-3136 or product candidates we may develop in the future, our commercial opportunities will be negatively impacted.

•We may be unable to obtain U.S. or foreign regulatory approvals and, as a result, may be unable to commercialize palazestrant, OP-3136 or any future product candidate we may develop.

•Unfavorable U.S. and global macroeconomic and geopolitical conditions could adversely affect our business, financial condition and results of operations.

•In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

•Our internal information technology systems, or those of any of our CROs, manufacturers, other contractors, consultants, collaborators, potential future collaborators, or other third parties (including service providers in our supply chain) may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data, or personal data, which could result in adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; or other adverse consequences.

•Our success depends on our ability to protect our intellectual property and our proprietary technologies.

•We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs to conduct certain aspects of our non-clinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize palazestrant, OP-3136 or future product candidates we may develop and our business, financial condition, results of operations and prospects could be significantly harmed.

•We qualify as a “smaller reporting company” within the meaning of the Exchange Act and may take advantage of certain exemptions from disclosure requirements available to smaller reporting companies, which could make our securities less attractive to investors and may make it more difficult to compare our performance to the performance of other public companies.

Risks related to our financial position and the need for additional capital

We have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.

We are a clinical-stage biopharmaceutical company, and we have no products approved for commercial sale, have not generated any revenue from product sales and have incurred losses since inception. To date, we have devoted substantially all of our resources and efforts to organizing and staffing our company, business planning, executing partnerships, raising capital, discovering, identifying and developing our lead product candidate, palazestrant (OP-1250), securing related intellectual property rights, conducting non-clinical studies, conducting a Phase 1/2 clinical study of palazestrant, initiating a Phase 3 clinical trial of palazestrant, and conducting non-clinical studies of OP-3136. We have not yet demonstrated our ability to obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for you to accurately predict our future success or viability than it could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by clinical-stage biopharmaceutical companies in rapidly

evolving fields. We also may need to transition from a company with a research focus to a company capable of successfully executing drug development activities and supporting commercial operations. If we do not adequately address these risks and difficulties or successfully make such a transition, our business, financial condition, results of operations and prospects will be significantly harmed.

We require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs of our product candidates or future commercialization efforts.

Developing pharmaceutical products, including conducting non-clinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses will increase in connection with our ongoing activities, particularly as we initiate and conduct clinical trials of, and seek marketing approval for, palazestrant. We anticipate incurring significant costs associated with the development of our lead product candidate, palazestrant, OP-3136 and any future product candidates we may develop. Our expenses could increase beyond expectations if we are required by the FDA, the European Medicines Agency, or the EMA, or other regulatory authorities to perform clinical trials or non-clinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. In addition, if we obtain marketing approval for palazestrant, OP-3136 or other product candidates, we expect to incur significant commercialization expenses related to drug sales, marketing, manufacturing and distribution. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop. We also incur costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations.

Our estimate as to how long we expect our existing cash, cash equivalents and marketable securities to be able to continue to fund our operating expenses and capital expenditures requirements is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control including a negative return on, our cash and cash equivalents, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Moreover, it is particularly difficult to estimate with certainty our future expenses given the dynamic nature of our business and the geopolitical and macroeconomic environment, generally, including economic uncertainty, market volatility, the ongoing Russia-Ukraine conflict and related sanctions, armed conflict between Israel and groups based in surrounding regions, inflation rates and the responses by central banking authorities to control such inflation, monetary supply shifts and related financial instability. Advancing the development of palazestrant, OP-3136 and any future product candidates we may develop will require a significant amount of capital, and our existing cash, cash equivalents and marketable securities will not be sufficient to fund all of the activities that are necessary to complete the development of palazestrant and OP-3136.

We will be required to obtain additional funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders, or cause our stock price to decline or restrict our operating activities. Adequate additional financing may not be available to us on acceptable terms, or at all. Market volatility, including as a result of geopolitical and macroeconomic events discussed above, could adversely increase our need to access capital and likewise, adversely impact our ability to access capital as and when needed. For example, inflation rates, particularly in the United States, recently increased to levels not seen in years, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital on acceptable terms, if at all. In addition, the U.S. Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation, which, coupled with reduced government spending and volatility in financial markets may have the effect of heightening these risks and further increasing economic uncertainty.

Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization

efforts. We also could be required to seek collaborators for palazestrant, OP-3136 or any future product candidate at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

We have incurred net losses since inception, and we expect to continue to incur net losses for the foreseeable future. In addition, we may be unable to continue as a going concern over the long term.

We have incurred net losses in each reporting period since our inception, have not generated any revenue from product sales to date and have financed our operations principally through sales of shares of our common stock pursuant to a sales agreement, or the Sales Agreement, with Cowen and Company, LLC, or TD Cowen, as sales agent pursuant to an at-the-market offering, or the ATM Shares, the private placement of 13,211,381 shares of our common stock, at a price of $9.84 per share, to selected institutional and accredited investors, or the Private Placement, our initial public offering and private financings. We have incurred net losses of $30.4 million and $20.1 million for the three months ended June 30, 2024 and 2023, respectively. We had an accumulated deficit of $367.0 million as of June 30, 2024. Our losses have resulted principally from expenses incurred in research and development of palazestrant and from management and administrative costs and other expenses that we have incurred while building our business infrastructure. Our lead product candidate, palazestrant, is in clinical trials. As a result, we expect that it will be several years, if ever, before we have a commercialized product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing palazestrant in one of our lead indications, we expect that we will continue to incur substantial research and development and other expenses as we continue the clinical development programs for palazestrant in other indications or for OP-3136.

While our expenses may fluctuate from period to period, we generally expect to continue to incur increased expenses and operating losses for the foreseeable future as we continue our research and development efforts and seek to obtain regulatory approval for palazestrant or OP-3136. The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our working capital. In any particular period, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

In addition, our condensed consolidated financial statements for the three months ended June 30, 2024 and 2023 included elsewhere in this Quarterly Report on Form 10-Q have been prepared assuming we will continue as a going concern. However, we have incurred losses and negative cash flows from operations. As a development stage company, we expect to incur significant and increasing losses until regulatory approval is granted for palazestrant or OP-3136. Regulatory approval is not guaranteed and may never be obtained. As a result, these conditions raise substantial doubt about our ability to continue as a going concern over the long term.

We have never generated revenue from product sales and may never be profitable.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with our collaboration partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, palazestrant, OP-3136 and any future product candidates we may develop. We do not anticipate generating revenue from product sales for the next several years, if ever. Our ability to generate revenue from product sales depends heavily on our and our current and potential future collaborators' success in:

- ocompleting clinical and non-clinical development of our product candidates and programs and identifying and developing new product candidates;
- oseeking and obtaining marketing approvals for any product candidates that we develop;

- olaunching and commercializing product candidates for which we obtain marketing approval by establishing a sales force, marketing, medical affairs and distribution infrastructure or, alternatively, collaborating with a commercialization partner;
- oachieving adequate access and reimbursement by government and third-party payors for product candidates that we develop;
- oestablishing and maintaining supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and the market demand for product candidates that we develop, if approved;
- oobtaining market acceptance of product candidates that we develop as viable treatment options;
- oaddressing any competing technological and market developments;
- onegotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations in such collaborations;
- omaintaining, protecting, enforcing and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- odefending against third-party interference, infringement or other intellectual property-related claims, if any; and
- oattracting, hiring and retaining qualified personnel.

Even if palazestrant, OP-3136 or any future product candidate that we may develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA, EMA or other comparable regulatory authorities to perform clinical trials or non-clinical studies in addition to those that we currently anticipate. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

The terms of the Loan Agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

In September 2023, we entered into a loan and security agreement, or the Original Loan Agreement, with Silicon Valley Bank, a division of First-Citizens Bank & Trust Company, or the Bank, providing us with an aggregate principal amount of up to $50.0 million, or the Original Credit Facility, of which $25.0 million was available as of June 30, 2024 and up to $25.0 million of which could have been made available upon approval of the Bank in its discretion.

In June 2024, we entered into the first amendment to loan and security agreement, or the Amendment, and together with the Original Loan Agreement, the Loan Agreement, with the Bank. The Amendment amends the Original Loan Agreement in order to, among other things, increase the aggregate principal amount of the Original Credit Facility from up to $50.0 million to up to $100.0 million, or the Credit Facility, of which $25.0 million is currently available, an additional $25.0 million which will become available upon achievement of certain milestones related to execution of a first-line pivotal Phase 3 clinical trial of palazestrant in combination with ribociclib, and an additional $50.0 million which may be made available upon approval of the Bank in its discretion. The Credit Facility will mature on July 1, 2028.

Our overall leverage and certain obligations and affirmative and negative covenants contained in the Loan Agreement and related documentation could adversely affect our financial health and business and future operations by limiting our ability to, among other things, satisfy our obligations under the Loan Agreement, refinance our debt on terms acceptable to us or at all, plan for and adjust to changing business, industry and market conditions, use our available cash flow to fund future acquisitions and make dividend payments, and

obtain additional financing for working capital, to fund growth or for general corporate purposes, even when necessary to maintain adequate liquidity.

If we default under the Loan Agreement, the Bank may accelerate all of our repayment obligations and exercise all of its rights and remedies under the Loan Agreement and applicable law, potentially requiring us to renegotiate our agreement on terms less favorable to us. Further, if we are liquidated, the lenders' right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. The Bank could declare a default upon the occurrence of customary events of default, including events that it interprets as a material adverse change as delineated in the Loan Agreement, payment defaults or breaches of certain affirmative or negative covenants, thereby requiring us to repay the loan immediately. Any declaration by the lender of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. Additionally, if we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

Risks related to the discovery, development and commercialization of our product candidates

We are substantially dependent on the success of our lead product candidate, palazestrant, which is currently in clinical development. If we are unable to complete development of, obtain regulatory approval for and commercialize palazestrant in one or more indications and in a timely manner, our business, financial condition, results of operations and prospects will be significantly harmed.

Our future success is heavily dependent on our ability to timely complete clinical trials, obtain marketing approval for and successfully commercialize palazestrant, our lead product candidate. We expect that a substantial portion of our efforts and expenses over the next several years will be devoted to the development of palazestrant in our ongoing clinical trials in multiple indications. We are investing significant efforts and financial resources in the research and development of palazestrant. Palazestrant will require additional clinical development, evaluation of clinical, non-clinical and manufacturing activities, marketing approval from regulatory authorities, and significant marketing efforts before we can generate any revenues from product sales. We are not permitted to market or promote palazestrant before we receive marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals. Should our planned clinical development of palazestrant in our lead indications fail to be completed in a timely manner or at all, we will need to rely on our ongoing and planned clinical development of palazestrant in additional indications, which will require more time and resources to obtain regulatory approval and proceed with commercialization and may ultimately be unsuccessful.

We cannot assure you that our planned clinical development programs for palazestrant will be completed in a timely manner, or at all, or that we will be able to obtain approval for palazestrant from the FDA, European Commission (based on the positive opinion of the EMA's Committee for Medicinal Products for Human Use), or any comparable foreign regulatory authority. If we are unable to complete development of, obtain regulatory approval for and commercialize palazestrant in one or more indications and in a timely manner, our business, financial condition, results of operations and prospects will be significantly harmed.

Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development. We have never completed a pivotal clinical trial or submitted a New Drug Application, or NDA, to the FDA or similar drug approval filings to comparable foreign authorities. If we are ultimately unable to obtain regulatory approval for palazestrant or OP-3136, we will be unable to generate product revenue and our business, financial condition, results of operations and prospects will be significantly harmed.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of non-clinical studies and clinical trials of palazestrant, OP-3136 and any future product candidates we may develop may not be predictive of the results of subsequent clinical trials. We have a limited operating history and to date have not demonstrated our ability to complete large-scale clinical trials.

Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through non-clinical studies and initial 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 biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we or any potential future collaborator may decide, or regulators may require us, to conduct additional clinical trials or non-clinical 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.

Our future clinical trials may not be successful. If any product candidate is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and our business, financial condition, results of operations and prospects may be significantly harmed. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols and the dropout rate among clinical trial participants. Patients treated with palazestrant, OP-3136 or product candidates we may develop in the future may also be undergoing surgical, radiation and chemotherapy treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to palazestrant, OP-3136 or product candidates we may develop. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market palazestrant, OP-3136 or any future product candidates we may develop.

We do not know whether our current clinical trial of palazestrant, OP-3136 or any future clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market palazestrant, OP-3136 or any future product candidates we may develop. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. If we are unable to bring palazestrant, OP-3136 or any future product candidates to market, our ability to create long-term stockholder value will be limited.

In addition, we may rely in part on non-clinical, clinical and quality data generated by CROs and other third parties for regulatory submissions for palazestrant or OP-3136. While we have or will have agreements governing these third parties' services, we have limited influence over their actual performance. If these third parties do not make data available to us, or, if applicable, make regulatory submissions in a timely manner, our development programs may be significantly delayed, and we may need to conduct additional studies or collect additional data independently. In either case, our development costs would increase.

Moreover, non-clinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in non-clinical studies and clinical trials nonetheless failed to obtain FDA, European Commission or comparable foreign regulatory authority approval. We cannot guarantee that the FDA or foreign regulatory authorities will interpret trial results as we do, and more trials could be required before we are able to submit an application seeking approval of palazestrant, OP-3136 or any future product candidates we may develop. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing approval, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of palazestrant, OP-3136 or any future product candidates we may develop. Even if regulatory approval is secured for palazestrant or OP-3136, the terms of such approval may limit the scope and use of palazestrant or OP-3136, which may also limit its commercial potential. Furthermore, the approval policies or regulations of the FDA, European Commission or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval, which may lead to the FDA, European Commission or comparable foreign regulatory authorities delaying, limiting or denying approval of palazestrant or OP-3136, including and any other indication we are seeking for approval under palazestrant or OP-3136.

The regulatory approval processes of the FDA, European Commission and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable

to obtain regulatory approval for palazestrant, OP-3136 or any future product candidates we may develop, our business, financial condition, results of operations and prospects will be significantly harmed.

The time required to obtain approval by the FDA, European Commission and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions.

Applications for palazestrant or OP-3136 could fail to receive regulatory approval for many reasons, including the following:

- the FDA, European Commission or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA, European Commission or other comparable foreign regulatory authorities may determine that palazestrant or OP-3136 is not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- the FDA, European Commission or other comparable foreign regulatory authorities may disagree with our interpretation of data from non-clinical studies or clinical trials;
- the data collected from clinical trials of palazestrant or OP-3136 may not be sufficient to support the submission of a NDA, or other submission or to obtain regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA, European Commission or other comparable foreign regulatory authorities that palazestrant's or OP-3136's risk-benefit ratio for its proposed indication is acceptable;
- the FDA, EMA, the European Commission, the competent authorities of EU Member States or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA, European Commission or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market palazestrant or OP-3136, which would significantly harm our business, financial condition, results of operations and prospects.

In addition, even if we obtain approval of palazestrant or OP-3136 for a lead indication, regulatory authorities may not approve palazestrant or OP-3136 for other indications, may impose significant limitations in the form of narrow indications, warnings, or a Risk Evaluation and Mitigation Strategy, or REMS, or comparable foreign strategy. Certain regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials or may approve palazestrant or OP-3136 with a label that does not include the labeling claims necessary or desirable for successful. In addition, regulatory authorities in certain countries may not approve the price we intend to charge for the product we develop. If we are unable to obtain regulatory approval of palazestrant or OP-3136, or if regulatory approval is limited, our business, financial condition, results of operation and prospects will be significantly harmed.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.

We may experience delays in clinical trials of palazestrant, OP-3136 or any future product candidate we may develop. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients, or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including delays related to:

- the FDA, EMA, the European Commission or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- obtaining regulatory authorizations to commence a trial or reaching a consensus with regulatory authorities on trial design;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval from one or more institutional review boards, or IRBs;
- IRBs refusing to approve or Ethics Committees issuing negative opinions, IRBs or Ethics Committees suspending, varying or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes to clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;
- manufacturing sufficient quantities of product candidates or obtaining sufficient quantities of combination therapies for use in clinical trials;
- subjects failing to enroll or remain in our trial at the rate we expect, or failing to return for post- treatment follow-up;
- subjects choosing an alternative treatment for the indication for which we are developing palazestrant or OP-3136, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;
- regulatory authorities imposing a clinical hold;
- disruptions at the FDA and other agencies or regulatory authorities, including as a result of legislative actions or a government shutdown;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- selection of clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;
- shutdowns, either temporarily or permanently, of any facility manufacturing palazestrant, OP-3136 or any future product candidate we may develop or any of their components, including by order from the FDA, competent authorities of EU Member States or comparable foreign regulatory authorities due to violations of current good manufacturing practice, or cGMP, regulations or other applicable

requirements, or infections or cross-contaminations of palazestrant, OP-3136 or any future product candidate we may develop in the manufacturing process;

•any changes to our manufacturing process that may be necessary or desired;

•third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices, or GCP, or other regulatory requirements;

•third-party contractors not performing data collection or analysis in a timely or accurate manner; or

•third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

We could also encounter delays if a clinical trial is suspended, varied or terminated by us, by the IRBs or Ethics Committees of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA, competent authorities of EU Member States or comparable foreign regulatory authorities. Such authorities may impose such a suspension, variation or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, competent authorities of EU Member States or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs, Ethics Committees, competent authorities of EU Member States for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as we may do for palazestrant, OP-3136 or product candidates we may develop in the future, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

If we experience delays in the completion of, or termination of, any clinical trial of palazestrant, OP-3136 or any product candidates we may develop in the future, the commercial prospects of palazestrant, OP-3136 or any product candidates we may develop in the future will be harmed, and our ability to generate product revenues from palazestrant, OP-3136 or any product candidates we may develop in the future will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down palazestrant's, OP-3136's or any product candidates we may develop in the future's development and approval process and jeopardize our ability to commence product sales and generate revenues.

In addition, many of the factors that cause, or lead to, termination, variation or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of palazestrant, OP-3136 or any product candidates we may develop in the future. Any delays in our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize palazestrant, OP-3136 or any product candidates we may develop in the future and our competitors may be able to bring products to market before we do, and the commercial viability of palazestrant, OP-3136 or any product candidates we may develop in the future could be significantly reduced. Any of these occurrences may significantly harm our business, financial condition, results of operations and prospects.

Although we have received Fast Track designation for palazestrant for ER+/HER2- metastatic breast cancer that has progressed following one or more lines of endocrine therapy with at least one line given

in combination with a CDK4/6 inhibitor, we may be unable to obtain or maintain the benefits associated with such designation.

In July 2022, we were granted FDA Fast Track designation for palazestrant for ER+/HER2- metastatic breast cancer that has progressed following one or more lines of endocrine therapy with at least one line given in combination with a CDK4/6 inhibitor. If a drug is intended for the treatment of a serious or life-threatening condition and demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for FDA Fast Track designation for a particular indication. NDAs submitted for Fast Track designated drugs may qualify for priority review, accelerated approval and rolling submission under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing approval by the FDA. In addition, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track designation does not provide assurance of ultimate FDA approval.

Because we are pursuing a variety of target indications for palazestrant, we may expend our limited resources to pursue a particular indication and fail to capitalize on indications or additional product candidates that may be more profitable or for which there is a greater likelihood of success.

We are currently focused on pursuing a variety of target indications for palazestrant, and we have expended, and plan to continue to expend, significant resources to pursue these and other indications for palazestrant. We also may in the future spend our resources on other research programs and product candidates for specific indications that ultimately do 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.

Because we have limited financial and managerial resources, we must focus our research and development efforts on those product candidates and specific indications that we believe are the most promising. As a result, we may forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities, which will significantly harm our business, financial condition, results of operations and prospects.

Even if approved, palazestrant or OP-3136 may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Even if palazestrant or OP-3136 receives regulatory approval, it may not gain adequate market acceptance among physicians, patients, healthcare payors and others in the medical community. The degree of market acceptance would depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- restrictions on the use of palazestrant or OP-3136, such as boxed warnings or contraindications in labeling, or a REMS, or comparable foreign strategy, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;

- our pricing and the availability of coverage and adequate reimbursement by third-party payors, including government authorities;
- the availability of palazestrant or OP-3136 for use as a combination therapy;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the effectiveness of sales and marketing efforts;
- unfavorable publicity relating to palazestrant, OP-3136 or similar approved products or product candidates in development by third parties; and
- the approval of other new therapies for the same indications.

If palazestrant or OP-3136 is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue, which could significantly harm our business, financial condition, results of operations and prospects.

If we experience delays or difficulties in the enrollment and/or maintenance of patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Patient enrollment is a significant factor in the timing of clinical trials, and the timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. We may not be able to initiate or continue clinical trials for palazestrant, OP-3136 or any future product candidate we may develop, if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA, EMA, the European Commission or other comparable foreign regulatory authorities. Additionally, certain clinical trials for future product candidates may be focused on indications with relatively small patient populations, which may further limit enrollment of eligible patients or may result in slower enrollment than we anticipate. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants.

Patient enrollment may also be affected if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as palazestrant, OP-3136 or any future product candidate we may develop, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' product candidates. Patient enrollment for any of our clinical trials may be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- efforts to facilitate timely enrollment in clinical trials;

- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients;
- continued enrollment of prospective patients by clinical trial sites;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion or, because they may be late-stage cancer patients, will not survive the full terms of the clinical trials; and
- the level of resources that clinical sites have to conduct a growing number of clinical studies.

Our inability to enroll and maintain a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for palazestrant, OP-3136 or any future product candidate we may develop and jeopardize our ability to obtain marketing approval for the sale of palazestrant, OP-3136 or any product candidate we may develop in the future. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining enrollment of such patients in our clinical trials.

We intend to develop palazestrant, and may develop OP-3136 or future product candidates, in combination with other therapies, which exposes us to additional risks.

We intend to develop palazestrant, and may develop OP-3136 or other future product candidates, in combination with one or more other approved or unapproved therapies to treat cancer or other diseases. For example, we have a Phase 1/2 clinical study of palazestrant in a combination trial with a CDK4/6 inhibitor, and additional Phase 1/2 clinical studies of palazestrant in combination with another CDK4/6 inhibitor and with a PI3Ka inhibitor.

Even if palazestrant, OP-3136 or any future 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 European Commission or comparable foreign 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 palazestrant, OP-3136 or any future product candidate we may develop, are replaced as the standard of care for the indications we choose for palazestrant, OP-3136 or any future product candidate we may develop, the FDA, the European Commission or comparable foreign 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 choose to evaluate palazestrant, OP-3136 or future product candidates in combination with one or more cancer therapies that have not yet been approved for marketing by the FDA, European Commission or comparable foreign regulatory authorities. We will not be able to market and sell palazestrant, OP-3136 or any future product candidate we may develop, in combination with an unapproved cancer therapy for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved cancer therapies face the same risks described with respect to palazestrant or OP-3136 currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA, European Commission or comparable foreign regulatory approval.

If the FDA, European Commission or comparable foreign regulatory authorities do not approve these other drugs or revoke their approval of, or if safety, efficacy, quality, manufacturing or supply issues arise with, the drugs we choose to evaluate in combination with palazestrant, OP-3136 or future product candidates we may develop, we may be unable to obtain approval of or market such combination therapy.

Risks associated with the in-licensing or acquisition of drug candidates could cause substantial delays in the preclinical and clinical development of our drug candidates.

We have previously in-licensed product candidates, and we may acquire or in-license potential product candidates for in the future, as we continue to build our pipeline. Such arrangements with third parties may impose diligence, development and commercialization obligations, milestone payments, royalty payments, indemnification and other obligations on us. Our obligations to pay milestone, royalty and other payments to our licensor may be substantial, and the amount and timing of such payments may impact our ability to progress the development and commercialization of our product candidates. Our rights to use any licensed intellectual property may be subject to the continuation of and our compliance with the terms of any such agreements.

Disputes over intellectual property and other rights that we have licensed or acquired, or may license or acquire in the future, from third parties could prevent or impair our ability to maintain any such arrangements on acceptable terms, result in delays in the commencement or completion of our preclinical studies and clinical trials and impact our ability to successfully develop and commercialize the affected product candidates. If we fail to comply with our obligations under any licensing agreements, these agreements may be terminated or the scope of our rights under them may be reduced and we might be unable to develop, manufacture or market any product that is licensed under these agreements.

The incidence and prevalence for target patient populations of palazestrant and OP-3136 are based on estimates and third-party sources. If the market opportunities for palazestrant, OP-3136 or any future product candidate we may develop, if and when approved, are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.

Periodically, we make estimates regarding the incidence and prevalence of target patient populations for particular diseases based on various third-party sources and internally generated analysis and use such estimates in making decisions regarding our drug development strategy, including acquiring or in-licensing product candidates and determining indications on which to focus in non-clinical or clinical trials.

The incidence and prevalence for target patient populations of palazestrant or OP-3136 are based on estimates and third-party sources. These estimates may be inaccurate or based on imprecise data. For example, the total addressable market opportunity will depend on, among other things, acceptance of our drugs by the medical community and patient access, drug pricing and reimbursement. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs, or new patients may become increasingly difficult to identify or gain access to. If the market opportunities for palazestrant, OP-3136 or any future product candidate we may develop, if and when approved, are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.

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

From time to time, we may publicly disclose preliminary or top-line data from our non-clinical studies and 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 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 top-line 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. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as

patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us has resulted and disclosure of interim data by us or by our competitors could in the future result in volatility in the price of our common stock.

Further, others, including regulatory authorities, 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 our particular product candidate or product 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, top-line, 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, palazestrant, OP-3136 or any future product candidates we may develop may be harmed, which could significantly harm our business, financial condition, results of operations and prospects.

We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than palazestrant, OP-3136 or product candidates we may develop in the future, our commercial opportunities will be negatively impacted.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products, product candidates and processes competitive with palazestrant or OP-3136. Any product candidate that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we are attempting to develop palazestrant and OP-3136. Products we may develop in the future are also likely to face competition from other products and therapies, some of which we may not currently be aware. In addition, palazestrant, OP-3136 and any product candidate that we may develop in the future may need to compete with off-label drugs used by physicians to treat the indications for which we seek approval. This may make it difficult for us to replace existing therapies with palazestrant, OP-3136 and any product candidate that we may develop in the future.

In particular, there is intense competition in the field of women's cancer which we are pursuing. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, emerging and start-up companies, government authorities, universities and other research institutions. We also compete with these organizations to recruit management, scientists and clinical development personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling subjects for clinical trials and in identifying and in-licensing new product candidates.

For example, if we are successful in developing palazestrant, it may compete against existing products and product candidates in development, to the extent any such product candidates are approved, for the treatment of estrogen receptor- positive, or ER+, breast cancer, including fulvestrant, marketed as Faslodex® by AstraZeneca PLC and or any generic equivalents of Faslodex® that are marketed or in development; elacestrant, marketed as ORSERDU™ by Stemline Therapeutics Inc.; giredestrant (GDC-9545), being developed by Roche Holding AG/Genentech, Inc.; camizestrant (AZD9833), being developed by AstraZeneca PLC; imlunestrant (LY3484356), being developed by Eli Lilly and Co.; vepdegestrant (ARV-471), being developed by Arvinas, Inc. in partnership with Pfizer, Inc.; and lasofoxifene, being developed by Sermonix Pharmaceuticals. There are also a number of KAT6 inhibitor product candidates in development that may compete with OP-3136 including PF-07248144, which is being developed by Pfizer.

We have chosen to initially address well-validated biochemical targets, and therefore expect to face competition from existing products and products in development. There are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. Many of these current and potential competitors may have significantly greater financial, manufacturing, commercial, clinical development, research and technical and human resources expertise than we do. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing biotechnology products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidate that we develop obsolete. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result of all of these factors, our competitors may succeed in obtaining approval from the FDA, the European Commission or other comparable foreign regulatory authorities or in discovering, developing and commercializing products in our field before we do.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, have a broader label, are marketed more effectively, receive greater levels of reimbursement or are less expensive than products we may develop. Our competitors also may obtain marketing approval from the FDA, the European Commission or other comparable foreign regulatory authorities for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Even if palazestrant, OP-3136 or other product candidates we may develop in the future achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. Technological advances or products developed by our competitors may render our technologies or palazestrant, OP-3136 or product candidates we may develop in the future obsolete, less competitive or not economical. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our product we may develop, if approved, would be adversely affected.

Changes in methods of palazestrant manufacturing or formulation may result in additional costs or delay.

As palazestrant progresses through non-clinical and clinical trials to potential marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause palazestrant to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of palazestrant and jeopardize our ability to commercialize palazestrant, if approved, and generate revenue.

Any product candidate we develop may become subject to unfavorable third-party coverage and reimbursement practices, as well as pricing regulations.

The availability and extent of coverage and adequate reimbursement by third-party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. If we obtain marketing approval of palazestrant, OP-3136 or any future product candidate we may develop, sales of such product will depend substantially, both in the United States and internationally, on the extent to which the costs of the product will be covered and reimbursed by third-party payors. If reimbursement is not available, or is available only at inadequate levels, we may not be able to successfully commercialize palazestrant, OP-3136 or any future product candidates we may develop. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate

return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, for example, principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our product to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular products and requiring substitutions of generic products and/or biosimilars. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our product. Nonetheless, palazestrant, OP-3136 or any future product candidates we may develop may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in European countries, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as palazestrant, OP-3136 or any future product candidates we may develop. In many countries, particularly European Union Member States, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of palazestrant, OP-3136 or any future product candidates we may develop to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for palazestrant, OP-3136 or any future product candidates we may develop. Accordingly, in markets outside the United States, the reimbursement for any product that we commercialize may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

If we are unable to establish or sustain coverage and adequate reimbursement for any product candidates that we commercialize from third-party payors, the adoption of those products and potential sales revenue would be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party payor reimbursement rates may change at any time.

Even if favorable coverage and reimbursement status is attained for a product for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Guidelines and recommendations published by various organizations can reduce the use of palazestrant, OP-3136 or any future product candidates we may develop.

Government authorities promulgate regulations and guidelines directly applicable to us and to palazestrant, OP-3136 or any future product candidates we may develop. In addition, professional societies, such as practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the healthcare and patient communities. Recommendations of government authorities or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of palazestrant, OP-3136 or any future product candidates we may develop or the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use of palazestrant, OP-3136 or any future product candidates we may develop.

Risks related to regulatory approval and other legal compliance matters

We may be unable to obtain U.S. or foreign regulatory approvals and, as a result, may be unable to commercialize palazestrant, OP-3136 or any future product candidate we may develop.

Palazestrant and OP-3136 are, and any product candidate we develop in the future will be, subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs. Rigorous non-clinical testing and clinical trials and an extensive regulatory approval process must be successfully completed in the United States and in many foreign jurisdictions before a new drug can be marketed. Satisfaction of these and other regulatory requirements is costly, time-consuming, uncertain and subject to unanticipated delays. We cannot provide any assurance that palazestrant, OP-3136 or any product candidate we may develop will progress through required clinical testing and obtain the regulatory approvals necessary for us to begin selling them.

We have not conducted, managed or completed large-scale or pivotal clinical trials nor managed the regulatory approval process with the FDA or any other regulatory authority. The time required to obtain approvals from the FDA and other regulatory authorities is unpredictable and requires successful completion of extensive clinical trials which typically takes many years, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA, EMA, the European Commission or other comparable foreign regulatory authorities use when evaluating clinical trial data can, and often does, change during drug development, which makes it difficult to predict with any certainty how they will be applied. We may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, or changes in FDA, EMA, the European Commission or other comparable foreign regulatory authorities' policies during the period of drug development, clinical trials and FDA, EMA, the European Commission or other comparable foreign regulatory authorities' regulatory review.

Any delay or failure in seeking or obtaining required approvals would have a material and adverse effect on our ability to generate revenue from the particular product candidate for which we are developing and seeking approval. Furthermore, any regulatory approval to market a drug may be subject to significant limitations on the approved uses or indications for which we may market the drug or the labeling or other restrictions. In addition, the FDA has the authority to require a REMS as part of approving a NDA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. These requirements or restrictions might include limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may significantly limit the size of the market for the drug and affect reimbursement by third-party payors.

We may also become subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials and manufacturing of palazestrant or OP-3136. The foreign regulatory approval process

varies among countries, and generally includes all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval.

Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage, such inability could significantly harm our business, financial condition, results of operations and prospects.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA, EMA, competent authorities of EU Member States, or other regulatory authority investigation of the safety and effectiveness of our product, our manufacturing processes and facilities or our marketing programs. The FDA, EMA, competent authorities of EU Member States or other regulatory authority investigations could potentially lead to a recall of our product or more serious enforcement action, limitations on the approved indications for which it may be used or suspension, variation, or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our product, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources and substantial monetary awards to trial participants or patients. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to marketing palazestrant or OP-3136, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could significantly harm our business, financial condition, results of operations and prospects.

Palazestrant, OP-3136 and any future product candidates we develop may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could inhibit regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.

As is the case with pharmaceuticals generally, there have been side effects and adverse events associated with the use of palazestrant, and it is likely that there may be additional side effects and adverse events associated with the use of palazestrant, OP-3136 or any future product candidates we may develop. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by palazestrant, OP-3136 or any future product candidates we may develop could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, the European Commission, or other comparable foreign regulatory authorities. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may significantly harm our business, financial condition, results of operations and prospects.

If palazestrant, OP-3136 or any future product candidates we may develop are associated with undesirable side effects or have unexpected characteristics in non-clinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete a trial or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may significantly harm our business, financial condition, results of operations and prospects.

Patients in our ongoing and planned clinical trials may in the future suffer significant adverse events or other side effects not observed in our non-clinical studies or previous clinical trials. Palazestrant, OP-3136 or any future product candidates we may develop, may be used as chronic therapies or be used in pediatric populations, for which safety concerns may be particularly scrutinized by regulatory authorities. In addition, if

palazestrant, OP-3136 or any future product candidates we may develop, are used in combination with other therapies, palazestrant, OP-3136 or any future product candidates we may develop may exacerbate adverse events associated with the therapy and it may not be possible to determine whether it was caused by our product or the one with which it was combined. Patients treated with palazestrant, OP-3136 or any future candidates we may develop, may also be undergoing surgical, radiation and chemotherapy treatments, which can cause side effects or adverse events that are unrelated to palazestrant, OP-3136 or any future product candidates we may develop, but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses.

If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, competent authorities of EU Member States, other comparable regulatory authorities or an IRB or Ethics Committee may suspend, vary or terminate clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could significantly harm our business, financial condition, results of operations and prospects. Further, if palazestrant or OP-3136 obtains marketing approval, toxicities associated with palazestrant or OP-3136 and not seen during clinical testing may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether palazestrant or OP-3136 will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on non-clinical studies or early-stage clinical trials.

The FDA, EMA, the European Commission and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

We currently plan to conduct international clinical trials and may choose to conduct additional international clinical trials in the future. The acceptance of study data by the FDA, EMA, the European Commission or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. 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 (1) the data are applicable to the United States population and United States medical practice; (2) the trials are performed by clinical investigators of recognized competence and pursuant to current GCP requirements; and (3) the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including the adequacy of the patient population studied and statistical powering, must be met. 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 the FDA, EMA, the European Commission or any applicable foreign regulatory authority will accept data from trials conducted outside of its applicable jurisdiction. If the FDA, EMA, the European Commission or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in palazestrant, OP-3136 or any future product candidates we may develop not receiving approval for commercialization in the applicable jurisdiction.

Obtaining and maintaining regulatory approval of palazestrant, OP-3136 or any product candidate we develop in the future, in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of palazestrant, OP-3136 or any product candidate we develop in the future, in other jurisdictions.

Obtaining and maintaining regulatory approval of palazestrant, OP-3136 or any product candidate we develop in the future, in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval

in any other jurisdiction. For example, even if the FDA, the European Commission or other foreign regulatory authority grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional non-clinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our product is also subject to approval.

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of palazestrant, OP-3136 or any product candidate we develop in the future, will be harmed.

Even if palazestrant, OP-3136 or any product candidate we develop in the future, receives regulatory approval, it will be subject to significant post-marketing regulatory requirements and oversight.

Any regulatory approvals that we may receive for palazestrant, OP-3136 or any product candidate we develop in the future, will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve palazestrant, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA, the European Commission or applicable foreign regulatory authorities approve palazestrant, OP-3136 or any product candidate we develop in the future, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for palazestrant or OP-3136 will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with cGMPs and GCP for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA, EU and other foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning letters;
- civil and criminal penalties;
- injunctions;
- suspension, variation or withdrawal of regulatory approvals;

- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on operations, including costly new manufacturing requirements.

The occurrence of any event or penalty described above may inhibit our ability to commercialize palazestrant, OP-3136 or any product candidate we may develop in the future and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of palazestrant, OP-3136 or any product candidate we may develop in the future. 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, and we may not achieve or sustain profitability.

The FDA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If palazestrant, OP-3136 or any future product candidate we may develop is approved for marketing, and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory authorities strictly regulate the promotional claims that may be made about prescription products, such as palazestrant, OP-3136 or any future product candidates we may develop, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory authorities as reflected in the product's approved labeling. If we receive marketing approval for palazestrant, OP-3136 or any future product candidates we may develop, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label based on the physician's independent medical judgment. If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. 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 cannot successfully manage the promotion of palazestrant, OP-3136 or any future product candidates we may develop, if approved, we could become subject to significant liability, which would significantly harm our business, financial condition, results of operations and prospects.

Disruptions at the FDA, EMA, the European Commission applicable foreign regulatory authorities, the SEC, and other government agencies and regulatory authorities caused by funding shortages or global health concerns could hinder their ability to hire and retain 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, or otherwise prevent those authorities from performing normal business functions on which the operation of our business may rely, which could significantly harm our business, financial condition, results of operations and prospects.

The ability of the FDA, EMA, the European Commission or any applicable foreign regulatory authority to review and approve new products can be affected by a variety of factors, including, as applicable government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes, and other events that may otherwise affect the FDA, EMA or any applicable foreign regulatory authority's ability to perform routine functions. Average review times at the authorities have fluctuated in recent years as a result and could be delayed. In addition, government funding of the SEC and other government authorities on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other authorities may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government authorities, which would adversely affect our business. If a

prolonged government shutdown occurs, or if global health concerns continue to 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 to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We may attempt to secure approval from the FDA, the European Commission or comparable foreign regulatory authorities through the use of accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional non-clinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive approval from the FDA, the European Commission or comparable foreign regulatory authorities through accelerated approval pathways, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA, the European Commission or comparable foreign regulatory authorities may seek to withdraw their approval.

We may in the future seek approval for palazestrant, OP-3136 or future product candidates we may develop through accelerated approval pathways. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. Third-party payors may refuse to provide coverage or reimbursement for the drug until the confirmatory studies are complete. Additionally, if such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug.

Prior to seeking accelerated approval for palazestrant or OP-3136, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or receive an expedited regulatory designation (e.g., breakthrough therapy designation) for palazestrant or OP-3136, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for palazestrant or OP-3136 would result in a longer time period to commercialization of such product candidate, could increase the cost of development of palazestrant or OP-3136 and could harm our competitive position in the marketplace.

We may face difficulties from changes to current regulations and future legislation.

Existing regulatory policies may change, and additional regulations may be enacted that could prevent, limit or delay regulatory approval of palazestrant, OP-3136 or any future product candidates we may develop. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. 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 and we may not achieve or sustain profitability.

For example, in March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, was passed, which substantially changed the way healthcare is financed by both the government and private insurers and continues to significantly impact the U.S. pharmaceutical industry. There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. In addition, 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 of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect until 2032 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on potential customers for our drugs, if approved, and accordingly, our business.

Moreover, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several presidential executive orders, 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 drug products.

For example, at the federal level, 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 pricing reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain high-expenditure single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights.

While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, on January 5, 2024, the FDA approved Florida's SIP proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. As an example, the regulatory landscape related to clinical trials in the EU has evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR permits trial sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision for each EU Member State. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment of some elements of the application by all EU Member States in which the trial is to be conducted, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State's decision is communicated to the sponsor through a centralized EU portal, the Clinical Trial Information System, or CTIS. The CTR provides a three-year transition period. The extent to which ongoing clinical trials will be governed by the CTR varies. For clinical trials in relation to which an application for approval was made on the basis of the Clinical Trials Directive before January 31, 2023, the CTD will continue to apply on a transitional basis until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. The CTR will apply to clinical trials from an earlier date if the related clinical trial application was made on the basis of the CTR or if the clinical trial has already transitioned to the CTR framework before January 31, 2025.

Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. This Health Technology Assessment ("HTA") of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. In December 2021, Regulation No 2021/2282 on HTA amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and will apply as of January 2025, is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation foresees a three-year transitional period and will permit EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected. In light of the fact that the United Kingdom ("UK") has left the EU, Regulation No 2021/2282 on HTA will not apply in the UK. However, the UK Medicines and Healthcare products Regulation Agency

("MHRA") is working with UK HTA bodies and other national organizations, such as the Scottish Medicines Consortium ("SMC"), the National Institute for Health and Care Excellence ("NICE"), and the All-Wales Medicines Strategy Group, to introduce new pathways supporting innovative approaches to the safe, timely and efficient development of medicinal products.

In addition, on April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation. If adopted in the form proposed, the recent European Commission proposals to revise the existing EU laws governing authorization of medicinal products may result in a decrease in data and market exclusivity opportunities for our product candidates in the EU.

We expect that the recent reform activity, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize palazestrant, OP-3136 or any future product candidates we may develop.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of palazestrant, OP-3136 or any future product candidates we may develop, if any, may be.

Our relationships with healthcare professionals, clinical investigators, CROs and third party payors 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 privacy and security laws (including health information privacy and security laws), which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of our product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our product for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal false claims and civil monetary penalties laws, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program

or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

•HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, also imposes obligations, including mandatory contractual terms, on covered entities including certain covered healthcare providers, health plans, and healthcare clearinghouses and their respective business associates and covered subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health information with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

•the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. The information reported is publicly available on a searchable website, with disclosure required annually; and

•analogous state and foreign laws and regulations, such as state and foreign anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third-party payors, including private insurers.

Outside the United States, interactions between pharmaceutical companies and health care professionals are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. For example, 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 EU Member States. In addition, payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, in some EU Member States agreements with healthcare professionals may be the subject of prior notification and approval by the healthcare professional's' public employer, his or her competent professional organization and/or the national competent regulatory authorities.

Some state and foreign laws require biotechnology companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Some state and foreign laws may require biotechnology companies to report information on the pricing of certain drug products. Some state and local laws may require the registration of pharmaceutical sales representatives.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve on-going substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, or comparable foreign programs integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance

with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials and sensitive third-party data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation ("EU GDPR"), the United Kingdom's GDPR ("UK GDPR"), impose strict requirements for processing personal data including, the collection and use of health data. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17.5 million British Pounds under the UK GDPR or, in each case, 4% of annual global revenue, whichever is higher; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws are considered 'inadequate'. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to effect such cross-border transfers of personal data in compliance with the EU GDPR and UK GDPR, such as the European Commission's 'Standard Contractual Clauses', the United Kingdom's 'International Data Transfer Agreement / Addendum', and the EU-U.S. Data Privacy Framework (which allows for transfers for relevant U.S.-based organizations who self-certify compliance and participate in the Framework), all such mechanisms are subject to legal challenges, and there is no assurance that we can always satisfy or rely on these mechanisms to lawfully effect cross-border transfers of personal data where required. If there is no lawful manner for us to effect or be the recipient of cross-border transfers of personal data in compliance with the EU GDPR and/or UK GDPR, and/or other applicable data privacy and security obligations, or if the requirements for a compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data to recipients outside the EEA for allegedly violating the EU GDPR's cross-border data transfer limitations. Additionally, companies that transfer personal data to recipients outside of the EEA and/or UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators individual litigants and activist groups.

In the United States, numerous federal and state laws and regulations, including state personal information laws, state data breach notification laws, and federal and state consumer protection laws and regulations govern the collection, use, disclosure and protection of personal information. For example, the California Consumer Privacy Act, or CCPA, went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain

personal information of consumers or households. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact certain of our business activities and may increase our compliance costs and potential liability.

Additionally, California voters approved a new privacy law, the California Privacy Rights Act, or CPRA, which went into effect on January 1, 2023. The CPRA significantly modifies the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. In addition, other states have enacted or proposed data privacy laws. For example, at least 11 states have passed comprehensive privacy laws that have or will go into effect. While some of these state laws, like the CCPA, exempt some data processed in the context of clinical trials, these laws demonstrate our vulnerability to the evolving regulatory environment related to personal information and make it difficult to predict the impact of such laws on our business or operations. Aspects of these state privacy statutes remain unclear, resulting in further legal uncertainty and potentially requiring us to modify our data practices and policies and to incur substantial additional costs and expenses in an effort to comply.

We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. Moreover, we publish privacy policies and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business, financial condition, results of operations and prospects.

Any actual or perceived failure by us or the third parties with whom we work to comply with these laws, regulations, or other obligations may lead to significant consequences, including but not limited to fines, penalties, regulatory investigations, lawsuits, significant costs for remediation, damage to our reputation, bans on processing personal data, orders to destroy or not use personal data, or other liabilities. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations.

Our employees and personnel may use generative artificial intelligence, or AI, technologies to perform their work, and the disclosure and use of personal information in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI, such as the EU AI Act. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and consumer lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

In addition to the possibility of fines, lawsuits, regulatory investigations, public censure, other claims and penalties, and significant costs for remediation and damage to our reputation, we could be materially and

adversely affected if legislation or regulations are expanded to require changes in our data processing practices and policies or if governing jurisdictions interpret or implement their legislation or regulations in ways that negatively impact our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

Any inability to adequately address data privacy or security-related concerns, even if unfounded, or to comply with applicable laws, regulations, standards and other obligations relating to data privacy and security, could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations. We attempt to mitigate the associated risks but there is no assurance that privacy and security-related safeguards will protect us from all risks associated with the third-party processing, storage and transmission of such information.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA or other comparable foreign regulations, provide accurate information to the FDA or other comparable regulatory authorities, comply with federal and state health care fraud and abuse laws and regulations and comparable foreign requirements, accurately report financial information or data or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could 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. It is not always possible to identify and deter misconduct by these 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 comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, or comparable foreign programs, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could significantly harm our business, financial condition, results of operations or prospects.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic

tort claims that may be asserted against us in connection with our storage or disposal of hazardous and flammable materials, including chemicals and biological materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.

Certain laws and regulations require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed or become more expensive.

Our business activities may be subject to the U.S. Foreign Corrupt Practices Act, or the FCPA, and similar anti-bribery and anti-corruption laws of other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

As we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits companies and their employees and third-party intermediaries from offering, promising, giving or authorizing the provision of anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, disgorgement, and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our product in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business.

In addition, our product and activities may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our product, or our failure to obtain any required import or export authorization for our product, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our product may create delays in the introduction of our product in international markets or, in some cases, prevent the export of our product to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or product targeted by such regulations, could result in decreased use of our product by, or in our decreased ability to export our product to existing or potential customers with

international operations. Any decreased use of our product or limitation on our ability to export or sell access to our product would likely significantly harm our business, financial condition, results of operations and prospects.

Risks related to employee matters, managing our growth and other risks related to our business

Unfavorable U.S. and global macroeconomic and geopolitical conditions could adversely affect our business, financial condition and results of operations.

Our results of operations could be adversely affected by general conditions in the U.S. and global economies, the U.S. and global financial markets and adverse geopolitical and macroeconomic developments, including the ongoing conflict between Ukraine and Russia and related sanctions, armed conflict between Israel and groups based in surrounding regions, labor shortages, inflation rates and the responses by central banking authorities to control inflation, monetary supply shifts and related financial instability. U.S. and global market and economic conditions have been, and continue to be, disrupted and volatile due to many factors, including component shortages and related supply chain challenges, geopolitical developments, including the events noted above. General business and economic conditions that could affect our business, financial condition or results of operations include fluctuations in economic growth, debt and equity capital markets, liquidity of the global financial markets, the availability and cost of credit, investor and consumer confidence, and the strength of the economies in which we, our manufacturers and our suppliers operate.

A severe or prolonged global economic downturn could result in a variety of risks to our business. For example, inflation rates, particularly in the United States, recently increased to levels not seen in years, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital on acceptable terms, if at all. In addition, the U.S. Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation, which, coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks. A weak or declining economy could also strain our manufacturers and other service providers in our supply chain, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. We are highly dependent on the management, research and development, clinical, financial and business development expertise of our executive officers, as well as the other members of our scientific and clinical teams.

Furthermore, although we have employment offer letters with each of our executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or employees. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the biotechnology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the future success of our business. We could in the future have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize palazestrant, OP-3136 or any other product candidate will be limited and the potential for successfully growing our business will be harmed.

If we are unable to establish sales or marketing capabilities or enter into agreements with third parties to sell or market palazestrant, OP-3136 or any product candidate we may develop in the future, we may not be able to successfully sell or market palazestrant, OP-3136 or any future product candidate we may develop that obtain regulatory approval.

We currently do not have, and have never had, a marketing or sales team. In order to commercialize any product candidates, if approved, we must build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell or market palazestrant, OP-3136 or any future product candidate we may develop. We may not be successful in accomplishing these required tasks.

Establishing an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize palazestrant, OP-3136 or any product candidate we may develop in the future will be expensive and time-consuming, and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of palazestrant, OP-3136 or any product candidate we may develop in the future that we obtain approval to market, if we do not have arrangements in place with third parties to provide such services on our behalf. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration. If we are unable to enter into such arrangements when needed, on acceptable terms, or at all, we may not be able to successfully commercialize palazestrant, OP-3136 or any product candidate we may develop in the future which may receive regulatory approval or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.

We have never commercialized a product candidate, and we currently have no sales force, marketing or distribution capabilities. To achieve commercial success for a product candidate, which we may license to others, we will rely on the assistance and guidance of those collaborators. For any product candidates for which we retain commercialization rights, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party.

Factors that may affect our ability to commercialize palazestrant, OP-3136 or any future product candidate we may develop, on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or our failure to educate physicians on the benefits of prescribing or ordering palazestrant, OP-3136 or any future product candidates we may develop and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of palazestrant, OP-3136 or any future product candidate we may develop. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of palazestrant, OP-3136 or any future product candidate we may develop, we may not generate revenues from such product candidate or be able to reach or sustain profitability.

In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of June 30, 2024, we had 89 employees, 80 of whom were full-time, including 54 employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, we expect to need additional managerial, operational, sales, marketing, financial and other

personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA, EMA and other comparable foreign regulatory authorities' review process for palazestrant, OP-3136 and any other future product candidates we may develop, while complying with any contractual obligations to contractors and other third parties we may have; and
- improving our operational, financial and management controls, reporting systems and procedures.

In addition, we expect to be conducting multiple clinical trials of palazestrant for several different indications as well as clinical trials for OP-3136 concurrently. Given the small size of our organization, we may encounter difficulties managing multiple clinical trials at the same time, which could negatively affect our ability to manage growth of our organization, particularly as we take on additional responsibility associated with being a public company. Our future financial performance and our ability to successfully develop and, if approved, commercialize, palazestrant, OP-3136 and any other future product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of clinical development and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third-party service providers is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of palazestrant, OP-3136 and any other future product candidates we may develop or otherwise advance our business. We cannot assure you that we will be able to manage our existing third-party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize palazestrant, OP-3136 and any other future product candidates we may develop and, accordingly, may not achieve our research, development and commercialization goals.

Our internal information technology systems, or those of any of our CROs, manufacturers, other contractors, consultants, collaborators, potential future collaborators, or other third parties (including service providers in our supply chain) may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data, or personal data, which could result in adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; or other adverse consequences.

In the ordinary course of our business, we and the third parties with whom we work, collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, processing) proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, trade secrets (collectively, sensitive information). Cyber-attacks, malicious internet-based activity, online and offline fraud, outages, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties with whom we work. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in

cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties with whom we work, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations.

We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing attacks, credential harvesting, personnel or vendor misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, attacks enhanced or facilitated by AI, and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, unavailability of, or access to our sensitive information or our information technology systems, or those of the third parties upon whom we rely. Despite the implementation of preventative and detective security measures, our internal computer systems and those of our current and any future CROs and other contractors, consultants, collaborators and third-party service providers that process our sensitive information, there can be no assurance that these measures will be effective.

We may not be able to anticipate all types of security incidents, and we may not be able to implement preventive measures effective against all such security incidents. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to run our business. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive information. We have in the past and may in the future be subject to security incidents. For instance, we have had company laptops containing corporate information stolen from company offices, though none of such instances have been material or caused material harm.

Moreover, in November 2021, we were alerted to an incident involving falsified information circulating on social media relating to our planned poster presentation for the Phase 1 dose-escalation portion of the ongoing Phase 1/2 clinical study of palazestrant at the San Antonio Breast Cancer Symposium. Additionally, the loss or compromise of clinical trial data from completed or future clinical trials could result in delays or revocation of our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. We also rely on third parties to manufacture palazestrant, and similar events relating to their computer systems could also have a material adverse effect on our business. We may have insufficient recourse against such third parties, and we may have to expend significant resources to mitigate the impact of such an event, to develop and implement protections to prevent future events of this nature from occurring, and to address other related concerns or issues. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations, the further development and commercialization of palazestrant or

OP-3136 could be delayed, and we could be subject to significant fines or penalties for any noncompliance with certain state, federal and/or international privacy and security laws.

Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure or security breach. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

EU drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our product in the European Member States.

We intend to seek approval to market palazestrant or OP-3136 in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for palazestrant or OP-3136, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of drugs is subject to governmental control and other market regulations which could put pressure on the pricing and usage of palazestrant or OP-3136. 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 palazestrant or OP-3136 will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for palazestrant or OP-3136 and may be affected by existing and future healthcare reform measures.

Moreover, in most foreign countries, including a number of EU Member States, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low-priced and high-priced Member States, can further reduce prices. An EU Member State may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Many EU Member States also periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. This Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States.

Legislators, policymakers and healthcare insurance funds in the EU may continue to propose and implement cost-containing measures to keep healthcare costs down, particularly due to the financial strain that the COVID-19 pandemic placed on national healthcare systems of EU countries. These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third-party payors. Further, an increasing number of EU and other foreign countries use prices for medicinal products established in other countries as reference prices to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our suppliers, CMOs, CROs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, public health pandemics or epidemics, and other natural or man-made disasters or business interruptions, for which we are predominantly self- insured. The occurrence of any of these business disruptions could seriously harm our operations, increase our costs and expenses and significantly harm our business, financial condition, results of operations and prospects.

Our ability to develop palazestrant, OP-3136 or any future product candidates we may develop could be disrupted if our operations or those of our suppliers are affected by man-made or natural disasters or other business interruptions. Our corporate headquarters are located in California near major earthquake faults and fire zones. The ultimate impact on us, our significant suppliers and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and business could suffer in the event of a major earthquake, fire or other natural disaster.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Our net operating loss, or NOL, carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or other restrictions. Under current U.S. federal tax law, federal NOL carryforwards generated in tax years ending on or prior to December 31, 2017, are only permitted to be carried forward for 20 taxable years and federal NOL carryforwards generated in tax years ending after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOL carryforwards is limited to 80% of current year taxable income. It is uncertain if and to what extent various states will conform to current U.S. federal tax law. For example, California recently enacted legislation that, with certain exceptions, suspends the ability to use California net operating losses to offset California income and limits the ability to use California business tax credits to offset California taxes, for taxable years beginning on or after January 1, 2024, and before January 1, 2027.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change” (generally defined as a cumulative change in our ownership by “5 percent shareholders” that exceeds 50 percentage points over a rolling three-year period), the corporation’s ability to use its pre-change NOL carryforwards and certain other pre-change tax attributes to offset its post-change income and taxes may be limited. Similar rules may apply under state tax laws. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result subsequent shifts in our stock ownership, some of which are outside our control. We have not conducted any studies to determine annual limitations, if any, that could result from such changes in the ownership. Our ability to utilize those NOL carryforwards could be limited by an “ownership change” as described above and consequently, we may not be able to utilize a material portion of our NOL carryforwards and certain other tax attributes, which could have a material adverse effect on our cash flows and results of operations.

A variety of risks associated with marketing palazestrant, OP-3136 or any future product candidate we may develop internationally could significantly harm our business, financial condition, results of operations and prospects.

We plan to seek regulatory approval of palazestrant, OP-3136 or any future product candidates we may develop outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements and reimbursement regimes in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may significantly harm our business, financial condition, results of operations and prospects.

Risks related to our intellectual property

Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection in the United States and other countries for palazestrant, OP-3136 and any future product candidates that we may develop and technologies related to their various uses. We generally seek to protect our proprietary position by, among other things, filing patent applications in the United States and abroad related to palazestrant, OP-3136, our proprietary technologies, and their manufacture and uses that are important to our business, as well as inventions and improvements that are important to the development and implementation of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position. We may also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending applications from third parties. If we or our potential licensors are unable to obtain or maintain patent protection with respect to palazestrant, OP-3136, proprietary technologies and their uses, our business, financial condition, results of operations and prospects could be significantly harmed.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties.

Moreover, in the future, some of our owned patents and patent applications, or any future licensed patents or patent applications, may be co-owned with third parties. If we are unable to obtain exclusive licenses to any such co-owners' interest in such patents or patent applications, then such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners to enforce such patents against third parties, and such cooperation may not be provided to us.

Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. Thus, the degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect the intellectual property rights relating to palazestrant, OP-3136 or any future product candidates we may develop could significantly harm our business, financial condition, results of operations and prospects.

We cannot be certain that the claims in our U.S. pending patent applications, and corresponding international patent applications, will be considered patentable by the United States Patent and Trademark Office, or USPTO, courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued patent(s) will not be found invalid or unenforceable if challenged.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting palazestrant, OP-3136 or any future product candidates we may develop by obtaining and defending patents. These risks and uncertainties include the following:

- patent applications must be filed in advance of certain events (*e.g.,* third party filings, certain sales or offers for sale, or other activities that might be legally deemed to be public disclosures) and we might not be aware of such events or otherwise might not succeed in filing applications before they occur;

- the USPTO and various foreign governmental patent authorities require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;

- patent applications may not result in any patents being issued;

- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;

- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States; and

- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

The patent prosecution process is also expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too

late to obtain patent protection, for example, if patentable aspects are publicly disclosed, by us or a third party, such as by public use, sale or offer for sale, or publication.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Further, although we require our employees, commercial contractors, and certain consultants and investigators to enter into invention assignment agreements that grant us ownership of any discoveries or inventions made by them while in our employ, we cannot guarantee that we have entered into such agreements with each party, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach such agreements and claim ownership in intellectual property that we believe is owned by us. In addition, 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 be certain that we were the first to make the inventions claimed in our owned or any licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Should any of the above events occur, it could significantly harm our business, financial condition, results of operations and prospects.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.

The patent positions of biopharmaceutical companies generally are highly uncertain, involve complex legal and factual questions for which important legal principles remain unsolved and have been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect palazestrant or OP-3136 or which effectively prevent others from commercializing competitive technologies and product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted after issuance. Legal standards relating to valid and enforceable claim scope are unsettled in the United States and elsewhere and disputes challenging or re-defining scope are common in the biopharmaceutical industry. Even if patent applications we own or in-license currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether palazestrant, OP-3136 or any future product candidates we may develop will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could significantly harm our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad.

The process by which patent applications are examined and considered for issuance as patents involves consideration by the relevant patent office of “prior art” relative to the invented technology. Different countries have different rules about what information or events can be considered “prior art,” and different requirements regarding when a patent application must be filed relative to any particular piece of potential prior art. Moreover, legal decisions can re-interpret or change whether particular information or events are considered to be “prior art.” Still further, in the United States, patent applicants are required to notify the USPTO of any material “prior

art" of which they are aware for the patent examiner to consider in addition to independent searches that the patent examiner is required to do. Also, in the United States and certain other jurisdictions, third parties are entitled to submit prior art to patent offices for consideration during examination.

We may not be aware of certain relevant prior art, may fail to identify or timely cite certain prior art, or may not be able to convince a patent examiner that our patent(s) should issue in light of the art. Also, we cannot be certain that all relevant art will be identified during examination of a patent application so that, even if a patent issues, it may be susceptible to challenge that it is not valid over art that was not considered during its examination.

We may be subject to a third-party pre-issuance submission of prior art to the USPTO or other jurisdictions, or become involved in post-grant challenges such as opposition, derivation, revocation, reexamination, post-grant review, or PGR, and inter partes review, or IPR, or other similar proceedings, or in litigation, challenging our patent rights, including by challenging the validity or the claim of priority of our patents. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize palazestrant, OP-3136 or any future product candidates we may develop and compete directly with us, without payment to us. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of palazestrant, OP-3136 or any future product candidates we may develop. 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, including art of which we were unaware, and art which was not raised during prosecution of any of our patent applications. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technology or platform, or any product candidates that we may develop. Such a loss of patent protection would significantly impact our business, financial condition, results of operations and prospects. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future product candidates or could embolden competitors to launch products or take other steps that could disadvantage us in the marketplace or draw us into additional expensive and time-consuming disputes. Should any of these events occur, it could significantly harm our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- we may not be able to detect infringement of our issued patents;
- others may be able to develop products that are similar to palazestrant, or any future product candidates we may develop, but that are not covered by the claims of the patents that we may in-license in the future or own;
- our competitors may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell palazestrant or any future product candidates we may develop;
- we, or our current or future collaborators or license partners, might not have been the first to make the inventions covered by the issued patents or patent application that we may in-license in the future or own;
- we, or our current or future collaborators or license partners, might be found not have been the first to file patent applications covering certain of our or their inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that the pending patent applications we may in-license in the future or own will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate our patents, or parts of our patents, for which we are not aware;
- issued patents that we hold rights to may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- issued patents may not have sufficient term or geographic scope to provide meaningful protection;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent in order to maintain certain trade secrets, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, it could significantly harm our business, financial condition, results of operations and prospects.

Our commercial success depends significantly on our ability to operate without infringing, misappropriating or otherwise violating the patents and other proprietary rights of third parties. Claims by third parties that we infringe, misappropriate or otherwise violate their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

Our commercial success depends in part on avoiding infringement, misappropriation or other violations of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe, misappropriate or otherwise violate patents or other intellectual property rights owned or controlled by third parties. A finding by a court or administrative body that we infringe the claims of issued patents owned by third parties could preclude us from commercializing palazestrant or any future product candidates we may develop.

Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import palazestrant, OP-3136 or any future product candidates we may develop and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, and proceedings, such as oppositions, reexaminations, IPR proceedings and PGR proceedings, before the USPTO and/or corresponding foreign patent offices. In addition, many companies in intellectual property-dependent industries, including the biopharmaceutical industry, have employed intellectual property litigation as a means to gain an advantage over their competitors. Numerous third-party U.S. and foreign issued patents and pending patent applications may exist in the fields in which we are developing palazestrant, OP-3136 or any future product candidates we may develop. There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of palazestrant, OP-3136 or any future product candidates we may develop. For example, we are aware of certain third-party patent applications and patents in the United States and abroad that include disclosure of chemical structures sharing certain similarities with palazestrant. It is possible that one or more of such third parties could pursue patent claims or assert patent claims that allegedly encompass palazestrant.

It is possible that one or more organizations will hold patent rights to which we will need a license. If those organizations refuse to grant us a license to such patent rights on reasonable terms, we may be unable to develop, manufacture, market, sell and commercialize products or services or perform research and development or other activities covered by these patents. In the event that any of these patents were to issue and be asserted against us, we believe that we would have defenses against any such assertion, including that such patents are not valid. However, if such defenses to such assertion were unsuccessful, we could be liable for damages, which could be significant and include treble damages and attorneys' fees if we are found to willfully infringe such patents. We could also be required to obtain a license to such patents, which may not be available on commercially reasonable terms or at all. If we are unable to obtain such a license, we could be precluded from commercializing any product candidates that were ultimately held to infringe such patents.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that palazestrant, OP-3136 or any future product candidates we may develop, may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published, we may be unaware of third-party patents that may be infringed by commercialization of palazestrant, OP-3136 or any future product candidates we may develop, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently-pending patent applications that may later result in issued patents that palazestrant, OP-3136 or any future product candidates we may develop may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. There is also no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Still further, we cannot rely on our experience that third parties have not so far alleged that we infringe their patent rights, as provisions of U.S. patent laws provide a safe harbor from patent infringement for therapeutic products under clinical development. If and when we submit an NDA that safe harbor will expire.

Any claims of patent infringement, misappropriation or other violations asserted by third parties would be time consuming and could:

- result in costly litigation that may cause negative publicity;
- cause development delays;
- prevent us from commercializing palazestrant, OP-3136 or any future product candidates we may develop;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Any patent-related legal action against us claiming damages or seeking to enjoin commercial activities relating to our products, or processes could subject us to significant liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or market palazestrant, OP-3136 or any future product candidates we may develop. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or a future strategic partner were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition,

we cannot be certain that we could redesign palazestrant, OP-3136 or any future product candidates we may develop processes to avoid infringement, if necessary.

An adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing palazestrant, OP-3136 or any future product candidates we may develop, which could significantly harm our business, financial condition and operating results. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing palazestrant, OP-3136 and future product candidates and technologies.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can. 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, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise significantly harm our business, financial condition, results of operations and prospects.

We may not be successful in obtaining or maintaining necessary rights from third parties for that we identify as necessary for palazestrant or OP-3136 through acquisitions and in-licenses.

Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights.

While we may have issued patents that cover palazestrant or OP-3136, it is possible that third parties may have blocking patents that prevent us from marketing, manufacturing or commercializing our own patented products and practicing our own patented technology.

We may be unsuccessful in acquiring or in-licensing compositions, methods of use, processes, or other intellectual property rights from third parties that we identify as necessary for practicing inventions claimed by our patents, including the manufacture, sale and use of palazestrant, OP-3136 and any future product candidates we may develop. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could significantly harm our business, financial condition, results of operations and prospects.

We may be involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court.

Competitors or other third parties may infringe, misappropriate or otherwise violate our intellectual property rights. To prevent infringement or unauthorized use, we may be required to file infringement or other intellectual property claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we may in-license in the future or own is not valid, is unenforceable, and/or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our owned patents or future in-licensed patents do not cover the technology in question. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at palazestrant, OP-3136 or any future product candidates we may develop, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity

challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, non-enablement, or obviousness-type double patenting. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

The outcome following legal assertions of invalidity and/or unenforceability is unpredictable, and prior art could render our patent invalid. There is no assurance that all potentially relevant prior art relating to our patent and patent applications has been found. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patent and patent applications, which may, nonetheless, ultimately be found 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 may lose at least part, and perhaps all, of the patent protection on such product candidate. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Such a loss of patent protection would significantly harm our business, financial condition, results of operations and prospects.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

Should any of these events occur, it could significantly harm our business, financial condition, results of operations and prospects.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could significantly harm our business, financial condition, results of operations and prospects.

Derivation proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party.

Derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party.

Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring palazestrant, OP-3136 or any future

product candidates to market. Should any of these events occur, it could significantly harm our business, financial condition, results of operations and prospects.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications or those of our licensors and the enforcement or defense of our issued patents or those of our licensors.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first inventor to file" system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013 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 such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. 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 or until issuance, we may not be certain that we or our licensors are the first to either (1) file any patent application related to palazestrant, OP-3136 or any future product candidate we may develop or (2) invent any of the inventions claimed in the patents or patent applications.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including PGR, IPR and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, 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. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications or those of our licensors and the enforcement or defense of our issued patents or those of our licensors, all of which could significantly harm our business, financial condition, results of operations and prospects.

Changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect palazestrant, OP-3136 or any future product candidates we may develop.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property. Such changes may also increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

Further, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening 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. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patent and the patents we might obtain or license in the future. Any of the foregoing could significantly harm our business, financial condition, results of operations, and prospects.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

It is possible that we do not perfect ownership of all patents, patent applications or other intellectual property. This possibility includes the risk that we do not identify all inventors, or identify incorrect inventors, which may lead to claims disputing inventorship or ownership of our patents, patent applications or other intellectual property by former employees or other third parties. There is also a risk that we do not establish an unbroken chain of title from inventors to us. Errors in inventorship or ownership can sometimes also impact priority claims. If we were to lose the ability to claim priority for certain patent filings, intervening art or other events may preclude us from issuing patents.

Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could significantly harm our business, financial condition, results of operations and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

Patent terms may be inadequate to protect our competitive position on palazestrant, OP-3136 or any future product candidates we may develop for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but there can be no assurance that any such extensions will be obtained, and the life of a patent, and the protection it affords, is limited. Even if patents covering palazestrant, OP-3136 or any future product candidates we may develop are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

In the United States, patent term can be adjusted due to delays that occur during examination of patent applications, which may extend the term of a patent beyond 20 years. There is a risk that we may take action that detracts from any accrued patent term adjustment.

It is necessary to pay certain maintenance fees, also referred to as annuities or renewal fees in some countries, throughout the lifetime of a patent at regular intervals. Failure to pay these fees can cause a granted patent to prematurely expire, without an opportunity for revival. There is a risk that we may be unable to maintain patent protection for certain patents in all markets due to finite availability of resources. Any of the foregoing could significantly harm our business, financial condition, results of operations and prospects.

If we do not obtain patent term extension for palazestrant, OP-3136 or any future product candidates we may develop, our business, financial condition, results of operations and prospects may be significantly harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of palazestrant, OP-3136 or any future product candidates we may develop, one or more of our U.S. patents or those of our licensors may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act

of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA approved product as compensation for the 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 and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of palazestrant, OP-3136 or any future product candidates we may develop. 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 restoration 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 business, financial condition, results of operations and prospects could be significantly harmed. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and non-clinical data and launch their product earlier than might otherwise be the case.

We will not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we will not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These infringing products may compete with palazestrant, OP-3136 or any future product candidates we may develop, without any available recourse.

The laws of some other countries do not protect intellectual property rights to the same extent as the laws of the United States. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biopharmaceuticals. As a result, many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. Because the legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceutical products, it could be difficult for us to stop the infringement, misappropriation or violation of our patents or our licensors' patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our intellectual property and other proprietary 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 or the patents of our licensors at risk of being invalidated or interpreted narrowly, could put our patent applications or the patent applications of our licensors 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. 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 develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government authorities or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be significantly harmed.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or patent applications. We have systems in place to remind us to pay these fees, and we rely on our outside patent annuity service to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are 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. If such an event were to occur, potential competitors might be able to enter the market with similar or identical products or technology, which could significantly harm our business, financial condition, results of operations and prospects.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business, financial condition, results of operations and prospects could be significantly harmed.

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. 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, competitors 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, financial condition, results of operations and prospects may be significantly harmed. 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 and could significantly harm our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business, financial condition, results of operations, prospects and competitive position would be significantly harmed.

In addition, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, 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 technology or processes. Further, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, or claim ownership in intellectual property that we believe is owned by us. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete

with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized. Any of the foregoing could significantly harm our business, financial condition, results of operations and prospects.

We may be subject to claims that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets.

We have entered into and may enter in the future into non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, potential partners, lessees of shared multi-company property and other third parties. Many of our employees and consultants were previously employed at, or may have previously provided or may be currently providing consulting services to, other biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may become subject to litigation where a third party asserts that we or our employees or consultants inadvertently or otherwise breached the agreements and used or disclosed trade secrets or other information proprietary to the third parties. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing palazestrant, OP-3136 or any future product candidates or technologies we may develop. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts, and cause us to lose valuable intellectual property rights or personnel, which could significantly harm our business, financial condition, results of operations and prospects. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Parties making claims against us may be able to sustain the costs of complex intellectual property litigation more effectively than we can. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise significantly harm our business, financial condition, results of operations and prospects.

Our rights to develop and commercialize our technology and product candidates may be subject, in part, to the terms and conditions of licenses granted to us by others.

We may enter into license agreements in the future with others to advance our research or allow commercialization of palazestrant, OP-3136 or any future product candidates we may develop. These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in our licenses.

If we fail to comply with our obligations under any such license agreements, including obligations to make various milestone payments and royalty payments and other obligations, the licensor may have the right to terminate the license. If these agreements are terminated, we could lose intellectual property rights that are important to our business, be liable for any damages to such licensors or be prevented from developing and commercializing our product candidates, and competitors could have the freedom to seek regulatory approval of, and to market, products identical to ours. Termination of these agreements or reduction or elimination of our rights under these agreements may also result in our being required to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, or impede, delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements. It is possible that we may be unable to obtain

any additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our product candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering the technology that we license from third parties. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business, including the payment of all applicable fees for patents covering our product candidates. If our licensors fail to prosecute, maintain, enforce and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are subject of such licensed rights could be adversely affected. Further, we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control the prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by the actions or inactions of our licensees, our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Our licensors may have relied on third party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

We may need to obtain additional licenses from existing licensors and others to advance our research or allow commercialization of product candidates we develop. It is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could significantly harm our business, financial condition, results of operations and prospects significantly. We cannot provide any assurances that third party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant. Should any of these events occur, it could significantly harm our business, financial condition, results of operations and prospects.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

Disputes may arise between us and our past, current or future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;

- our right to transfer or assign the license;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could significantly harm our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could significantly harm our business, financial condition and prospects.

In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. This could significantly harm our competitive position, business, financial condition and prospects.

Intellectual property discovered through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

We may develop, acquire, or license intellectual property rights that have been generated through the use of U.S. government funding or grants. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non- transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). If the U.S. government exercised its march-in rights in our future intellectual property rights that are generated through the use of U.S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. Any exercise by the government of any of the foregoing rights could harm our competitive position, business, financial condition, results of operations and prospects.

Risks related to our dependence on third parties

We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct certain aspects of our non-clinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize palazestrant, OP-3136 or future product candidates we may develop and our business, financial condition, results of operations and prospects could be significantly harmed.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators and third-party CROs, to conduct certain aspects of our non-clinical studies and clinical trials and to monitor and manage data for our ongoing non-clinical and clinical programs. We rely on these parties for execution of our non-clinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for palazestrant or OP-3136 in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. 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 adversely affected if any of these third parties violates federal, state or foreign fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Further, these investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to palazestrant and clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If independent investigators or CROs fail to devote sufficient resources to the development of palazestrant or OP-3136, or if CROs 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, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize palazestrant or OP-3136. As a result, our results of operations and the commercial prospects for palazestrant or OP-3136 would be harmed, our costs could increase and our ability to generate revenues could be delayed or precluded entirely, and our business, financial condition, results of operations and prospects could be significantly harmed.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Additionally, CROs may lack the capacity to absorb higher workloads or take on additional capacity to support our needs. There can be no assurance that we will not encounter challenges or delays with CROs in the future or that these delays or challenges will not significantly harm our business, financial condition, results of operations and prospects.

We contract with third parties for the manufacture of palazestrant for non-clinical studies and our ongoing clinical trials, and expect to continue to do so for additional clinical trials and ultimately for

commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of palazestrant or other drugs necessary for the development or commercialization of palazestrant or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently have the infrastructure or internal capability to manufacture supplies of palazestrant for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of palazestrant for non-clinical studies and clinical trials under the guidance of members of our organization. We do not have long-term supply agreements for palazestrant. Furthermore, the raw materials for palazestrant are sourced, in some cases, from a single-source supplier. If we were to experience an unexpected loss of supply of palazestrant for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials.

We expect to continue to rely on third-party manufacturers for the commercial supply of palazestrant, if we obtain marketing approval. We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture palazestrant according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over palazestrant or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- disruptions resulting from the impact of public health pandemics or epidemics;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the failure of the third party to manufacture palazestrant according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

We have limited control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EU or other foreign regulatory requirements, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, competent authorities of EU Member States or a comparable foreign regulatory authority does not approve these facilities for the manufacture of palazestrant, or if it withdraws any such approval in the future, we may need to find

alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market palazestrant, if approved. We, or our contract manufacturers, any future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA, competent authorities of EU Member States, or other comparable foreign regulatory authorities, to monitor and ensure compliance with cGMP. Despite our efforts to audit and verify regulatory compliance, one or more of our third-party manufacturing vendors may be found on regulatory inspection by the FDA, competent authorities of EU Member States or other comparable foreign regulatory authorities to be noncompliant with cGMP regulations. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including shutdown of the third-party vendor or invalidation of drug product lots or processes, fines, injunctions, civil penalties, delays, suspension, variation or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of palazestrant or other drugs necessary for the development or commercialization of palazestrant and significantly harm our business, financial condition, results of operations and prospects.

Furthermore, if the third-party providers of therapies or therapies in development used in combination with palazestrant are unable to produce sufficient quantities for clinical trials or for commercialization of palazestrant, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would significantly harm our business, financial condition, results of operations and prospects. For example, for our Phase 1b/2 clinical study of palazestrant in combination with KISQALI® (ribociclib) or PIQRAY® (alpelisib), or the Novartis Study Drugs, in patients with metastatic ER+ breast cancer, we entered into an Amended and Restated Clinical Collaboration and Supply Agreement with Novartis Institutes for BioMedical Research, Inc., or Novartis, as amended by Amendment No. 1 to Amended and Restated Clinical Collaboration and Supply Agreement between us and Novartis, and Amendment No. 2 to Amended and Restated Clinical Collaboration and Supply Agreement between us and Novartis, or, as amended, the Novartis Agreement. Under the terms of the Novartis Agreement, Novartis is providing KISQALI® (ribociclib) and PIQRAY® (alpelisib) for the clinical trial. If Novartis is unable to timely manufacture or provide KISQALI® (ribociclib) or PIQRAY® (alpelisib), or if the Novartis Agreement terminates and we are unable to obtain KISQALI® (ribociclib) or PIQRAY® (alpelisib) on the current terms, our Phase 1b/2 clinical study may be delayed and the cost to us to conduct this trial may significantly increase, which would significantly harm our business, financial condition, results of operations and prospects. For a description of the Novartis Agreement, see Note 10 to our notes to the condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q Financial Statements.

Our current and anticipated future dependence upon others for the manufacture of palazestrant or other drugs necessary for the development or commercialization of palazestrant may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

The manufacture of drugs is complex, and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of palazestrant for clinical trials or our product for patients, if approved, could be delayed or prevented.

Manufacturing drugs, especially in large quantities, is complex and may require the use of innovative technologies. Each lot of an approved drug product must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing drugs requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide non-clinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and significantly harm our business, financial condition, results of operations and prospects. The use of biologically derived ingredients can also lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination. If our manufacturers are unable to produce

sufficient quantities for clinical trials or for commercialization as a result of these challenges, or otherwise, our development and commercialization efforts would be impaired, which would significantly harm our business, financial condition, results of operations and prospects.

We have engaged in and may in the future engage in additional acquisitions, strategic partnerships or in-licensing opportunities, that may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We have engaged in the past and may in the future engage in or evaluate various acquisition opportunities, strategic partnerships and in-licensing opportunities, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risk of delay in receiving or the failure to receive anticipated benefits of any such transactions, or of facing unanticipated challenges;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions or pursue partnerships or in-licensing opportunities in the future, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may devote substantial resources and fail to realize the anticipated benefits of such efforts, or we may incorrectly judge the value of an acquired or in-licensed product candidate, technology or other asset. Any such failure to realize the anticipated benefits of any or all of our acquisitions, strategic partnerships or in-licensing opportunities in the time frame expected, or at all, could result in additional costs or loss of revenue. Furthermore, we may not be able to locate suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

We have entered into collaborations with third parties for the development and commercialization of palazestrant. If those collaborations are not successful, we may not be able to capitalize on the market potential of palazestrant.

We have third-party collaborators for the development and commercialization of palazestrant. Our likely collaborators for any future collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies.

We have, and will likely continue to have, limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of palazestrant. 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. Collaborations involving palazestrant could pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may deemphasize or not pursue development and commercialization of palazestrant or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates 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 palazestrant 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;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;
- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of palazestrant or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all; and
- if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our drug development or commercialization program could be delayed, diminished or terminated.

If we decide to establish collaborations in the future but are not able to establish those collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of palazestrant, OP-3136 or any future product candidates we may develop will require substantial additional cash to fund expenses. We may continue to seek to selectively form collaborations to expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.

If we seek collaborations in the future, we will face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, European Commission or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for palazestrant, OP-3136 or any future product candidates we may develop. Further, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Even if we are successful in entering into a collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators.

If and when we seek to enter into additional collaborations, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop palazestrant, OP-3136 or any future product candidates we may develop or bring them to market and generate product revenue.

Risks related to ownership of our common stock

An active trading market for our common stock may not be sustained.

Our common stock is currently listed on The Nasdaq Global Select Market under the symbol "OLMA." However, we cannot assure you that an active trading market for our common stock will be sustained. Accordingly, we cannot assure you of the liquidity of any trading market, your ability to sell your shares of our common stock when desired, or the prices that you may obtain for your shares. Further, an inactive market may also impair our ability to raise capital by selling our common stock and may impair our ability to enter into strategic partnerships or acquire businesses, products, or technologies using our common stock as consideration.

The price of our stock has been and may continue to be volatile, and you could lose all or part of your investment.

The trading price of our common stock has been and may continue to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. For example, the closing price of our common stock from January 1, 2023 to August 2, 2024 has ranged from a low of $2.55 to a high of $17.14. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q, these factors include:

- the timing and results of non-clinical studies and clinical trials of palazestrant, OP-3136 or any future product candidates we may develop or those of our competitors;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- regulatory actions with respect to our product candidates or our competitors' products;
- actual or anticipated changes in our growth rate relative to our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the pharmaceutical and biotechnology sector;
- changes in the structure of healthcare payment systems;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders; and
- general geopolitical, macroeconomic, industry and market conditions, including the ongoing conflict between Ukraine and Russia and related sanctions, armed conflict between Israel and groups based in surrounding regions, labor shortages, inflation rates and the responses by central banking authorities to control such inflation, monetary supply shifts and related financial instability.

In addition, the trading prices for common stock of other biopharmaceutical companies have been highly volatile as a result of factors unrelated to the specific company or its technology.

The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock.

Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- timing and variations in the level of expense related to the ongoing development of palazestrant, OP-3136 or future development programs;
- timing and status of enrollment for our clinical trials;
- impacts from geopolitical and macroeconomic events on us or third parties with which we engage;
- results of clinical trials, or the addition or termination of clinical trials or funding support by us or potential future partners;
- our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under potential future arrangements or the termination or modification of any such potential future arrangements;
- any intellectual property infringement, misappropriation or violation lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if palazestrant, OP-3136 or any future product candidate we may develop receive regulatory approval, the timing and terms of such approval and market acceptance and demand for such product candidates;
- the timing and cost to establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with current or future collaborators;
- regulatory developments affecting palazestrant, OP-3136 or any future product candidate we may develop or those of our competitors; and
- changes in general market and economic conditions.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors, significant stockholders and their respective affiliates beneficially own a significant percentage of our common stock. Therefore, these stockholders are able to significantly influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including

seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Our common stock price could decline as a result of sales of a large number of shares of common stock or the perception that these sales could occur. These sales, or the possibility that these sales may occur, might also make it more difficult for us to sell equity securities in the future at a time and price that we deem appropriate.

As of June 30, 2024, we had 57,246,411 shares of common stock outstanding. Shares issued upon the exercise of stock options and warrants outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, and Rules 144 and 701 under the Securities Act.

We were obligated to file a registration statement with the Securities and Exchange Commission to register all of the shares issued in the Private Placement for public resale, and are required to maintain effectiveness of that registration statement until the earliest of (i) the second anniversary of the effective date of such registration statement, (ii) such time as all of the shares issued in the Private Placement have been sold pursuant to such registration statement, or (iii) such time as the shares issued in the Private Placement become eligible for resale by non-affiliates without any volume limitations or other restrictions pursuant to Rule 144(b)(1)(i) under the Securities Act or any other rule of similar effect. We also register the offer and sale of all shares of common stock that we may issue under our equity compensation plans. Once we register the offer and sale of shares for the holders of registration rights and shares that may be issued under our equity incentive plans, these shares will be able to be sold in the public market upon issuance, subject to applicable securities laws.

In addition, in the future, we may issue additional shares of common stock, or other equity or debt securities convertible into common stock, in connection with a financing, acquisition, employee arrangement or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to palazestrant, OP-3136 or future product candidates we may develop on unfavorable terms to us.

We have in the past, and may again in the future seek additional capital through a variety of means, including through public or private equity, debt financings or other sources, including up-front payments and milestone payments from strategic collaborations. For example, in September 2023, we entered into the Private Placement, and in January 2024, we entered into the Sales Agreement with TD Cowen pursuant to which we may offer and sell, from time to time through TD Cowen, at our option, shares of our common stock having an aggregate offering price of up to $150.0 million. During the six months ended June 30, 2024, the Company issued 1,772,278 shares of its common stock under the Sales Agreement. To the extent that we raise additional capital through the sale of equity or convertible debt or equity securities, including pursuant to sales under the Sales Agreement, your ownership interest will be diluted, our stock price could fall and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Such financing may result in dilution to stockholders, imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to palazestrant or future product candidates we may develop, or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

We qualify as a "smaller reporting company" within the meaning of the Exchange Act and may take advantage of certain exemptions from disclosure requirements available to smaller reporting companies, which could make our securities less attractive to investors and may make it more difficult to compare our performance to the performance of other public companies.

Because our annual revenue was less than $100.0 million during the most recently completed fiscal year and the market value of our voting and non-voting common stock held by non-affiliates was less than $700.0 million measured on the last business day of our second fiscal quarter for the year ended December 31, 2023, we qualify as a "smaller reporting company" as defined in the Exchange Act. We may take advantage of certain of the scaled disclosures available to smaller reporting companies including, among other things, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, or Section 404, presenting only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and presenting reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict whether investors will find our securities less attractive because we will rely on these exemptions. If some investors find our securities less attractive as a result of our reliance on these exemptions, the trading prices of our securities may be lower than they otherwise would be, there may be a less active trading market for our securities and the trading prices of our securities may be more volatile.

New or future changes to tax laws could materially adversely affect our company.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the United States recently passed the Inflation Reduction Act, which provides for a minimum tax equal to 15% of the adjusted financial statement income of certain large corporations, as well as a 1% excise tax on certain share buybacks by public corporations that would be imposed on such corporations. In addition, it is uncertain if and to what extent various states will conform to federal tax legislation. The impact of such changes or future legislation could increase our U.S. tax expense and could have a material adverse impact on our business and financial condition. In addition, the pricing of our intercompany transactions may be challenged by taxing authorities, with potential increases in income and other taxes that could impact our business and financial condition.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which holders of our common stock might otherwise receive a premium. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our Board of Directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors. Among other things, these provisions:

- establish a classified Board of Directors such that not all members of our Board of Directors are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our Board of Directors;
- limit the manner in which stockholders can remove directors from our Board of Directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our Board of Directors;

- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- prohibit our stockholders from calling a special meeting of our stockholders;
- prohibit cumulative voting;
- authorize our Board of Directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called "poison pill," that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board of Directors; and
- require the approval of the holders of at least 66 2⁄3% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our amended and restated certificate of incorporations or amended and restated bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which prohibits a person who owns 15% or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired 15% or more of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of fiduciary duty;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine or otherwise related to our internal affairs.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such

action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

This exclusive-forum provision may limit a stockholder'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 and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business, financial condition, results of operations and prospects.

We do not currently intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation of the value of our common stock.

We have never declared or paid any cash dividends on our equity securities. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the terms of the Loan Agreement restrict our ability to declare and pay dividends. Any return to stockholders will therefore be limited to any appreciation in the value of our common stock, which is not certain.

General risk factors

The requirements of being a public company may strain our resources, result in more litigation and divert management's attention.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Stock Market LLC and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will continue to increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control and procedures on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could significantly harm our business, financial condition, results of operations and prospects. We may also need to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business, financial condition, results of operations and prospects may be significantly harmed.

These rules and regulations may make it more expensive for us to obtain director and officer liability insurance and, in the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our Board of Directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

In addition, as a result of our disclosure obligations as a public company, our business and financial condition has become more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. In addition, the market price of our common stock has been and may continue to be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation and stockholder derivative actions. We may be the target of these types of litigation and claims in the future. Even if any such claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management's resources and seriously harm our business, financial condition, results of operations and prospects.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls 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. Overall, we will continue with the implementation of additional measures around internal controls, and these will require validation and testing of the design and operating effectiveness of internal controls over a sustained period of financial reporting cycles. If we are unable to avoid future material weaknesses, our operations, financial reporting, or financial results could be harmed. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

If securities or industry analysts do not publish research or reports, or if they publish adverse or misleading research or reports, regarding us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that securities or industry analysts publish about us, our business or our market. If any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our intellectual property, our stock performance or our market, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Recent Sales of Unregistered Securities

There were no sales of equity securities during the period covered by this report that were not registered under the Securities Act and were not previously reported in a Current Report on Form 8-K filed by the Company.

Use of Proceeds from our Initial Public Offering of Common Stock

In November 2020, our Registration Statement on Form S-1 (No. 333-249748) was declared effective by the SEC and we issued and sold an aggregate of 12,650,000 shares of common stock (inclusive of 1,650,000 shares of common stock pursuant to the underwriters' exercise of their option to purchase additional shares) at a public offering price of $19.00 per share for aggregate net cash proceeds of approximately $220.6 million, after deducting underwriting discounts, commissions and offering costs. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

The sale and issuance of 12,650,000 shares in the IPO closed on November 23, 2020, J.P. Morgan Securities LLC, Jefferies LLC and Cowen and Company, LLC acted as joint book-running managers for the offering.

There were no material changes in the planned use of proceeds from the IPO from that described in the prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on November 19, 2020. As of June 30, 2024, we have used 100% of the net proceeds from the IPO.

Repurchase of Shares of Company Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description	Incorporated by Reference			
		Schedule Form	File Number	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation.	8-K	001-39712	3.1	11/23/2020
3.2	Amended and Restated Bylaws.	8-K	001-39712	3.1	12/16/2022
10.1*¥	First Amendment to Loan and Security Agreement by and between the Registrant and Silicon Valley Bank, a division of First-Citizens Bank & Trust Company, dated June 28, 2024				
10.2*	Olema Pharmaceuticals, Inc. Amended and Restated Non-Employee Director Compensation Policy				
31.1*	Certification of Chief Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Chief Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1*#	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document				
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents				
104	Cover page formatted as Inline XBRL and contained in Exhibit 101				

* Filed herewith.

The certifications attached as Exhibit 32.1 accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed “filed” by the Registrant for purposes of Section 18 of the Exchange Act, and are not to be incorporated by reference into any of the Registrant’s filings under the Securities Act, irrespective of any general incorporation language contained in any such filing.

¥ Pursuant to Item 601(b)(10) of Regulation S-K, portions of this exhibit have been omitted as the Registrant has determined that the omitted information is the type that the Registrant customarily and actually treats as private or confidential and is not material.

SIGNATURES

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

Olema Pharmaceuticals, Inc.

Date: August 6, 2024

By: /s/ Sean Bohen, M.D., Ph.D.
Sean Bohen, M.D., Ph.D.
President and Chief Executive Officer
(*Principal Executive Officer*)

Date: August 6, 2024

By: /s/ Shane Kovacs
Shane Kovacs
Chief Operating and Financial Officer
(*Principal Financial Officer and Principal Accounting Officer*)

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Exhibit 10.1

FIRST AMENDMENT
TO
LOAN AND SECURITY AGREEMENT

This First Amendment to Loan and Security Agreement (this "Amendment") is entered into this 28th day of June, 2024, by and between **SILICON VALLEY BANK, A DIVISION OF FIRST-CITIZENS BANK & TRUST COMPANY** ("**Bank**") and **OLEMA PHARMACEUTICALS, INC.**, a Delaware corporation ("**Borrower**").

RECITALS

A. Bank and Borrower have entered into that certain Loan and Security Agreement dated as of September 5, 2023 (as the same may from time to time be amended, modified, supplemented or restated, the "Loan Agreement").

B. Bank has extended credit to Borrower for the purposes permitted in the Loan Agreement.

C. Borrower has requested that Bank amend the Loan Agreement to (i) add a new 2024 Term Loan and (ii) make certain other revisions to the Loan Agreement as more fully set forth herein.

D. Bank has agreed to so amend certain provisions of the Loan Agreement, but only to the extent, in accordance with the terms, subject to the conditions and in reliance upon the representations and warranties set forth below.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1.Definitions. Capitalized terms used but not defined in this Amendment shall have the meanings given to them in the Loan Agreement.

2.Amendments to Loan Agreement.

2.1.Section 1.1 (Term Loan). Section 1.1(a) of the Loan Agreement is amended in its entirety and replaced with the following:

" (a) Availability. Subject to the terms and conditions of this Agreement, upon Borrower's request, during Draw Period A, Bank shall make term loan advances in an amount not exceeding the Term A Loan Availability Amount (each such advance is referred to herein as a "**Term A Loan Advance**" and, collectively, as the "**Term A Loan Advances**"). Subject to the terms and conditions of this Agreement, upon Borrower's request, during Draw Period B, Bank shall make term loan advances in an amount not exceeding the Term B Loan Availability

Amount (each such advance is referred to herein as a "**Term B Loan Advance**" and, collectively, as the "**Term B Loan Advances**"). Subject to the terms and conditions of this Agreement, upon Borrower's request, during Draw Period C, Bank shall make term loan advances in an amount not exceeding the Term C Loan Availability Amount (each such advance is referred to herein as a "**Term C Loan Advance**" and, collectively, as the "**Term C Loan Advances**"). The Term A Loan Advances, the Term B Loan Advances, and the Term C Loan Advances are each referred to herein as a "**Term Loan Advance**" and, collectively, as the "**Term Loan Advances**". Borrower may request Term Loan Advances as set forth on Schedule I hereto."

2.2.Section 5.7(a) (Accounts). Section 5.7(a) is amended in its entirety and replaced with the following:

" (a) Maintain (i) at least one (1) operating account at Bank and (ii) account balances in the name of Borrower at Bank which represent at least 50.0% (excluding the account balance maintained in the Permitted JPM Operating Account) of the Dollar value of Borrower's, its Subsidiaries, and any Guarantor's cash, wherever located (the "**Account Threshold**"). So long as Borrower is in compliance with the Account Threshold, Borrower shall be permitted to maintain accounts with financial institutions other than Bank (individually, a "**Permitted Account**" and collectively, the "**Permitted Accounts**"), provided that each Permitted Account shall be subject to a Control Agreement in favor of Bank pursuant to the terms of Section 5.7(c). In addition to the foregoing, Borrower shall at all times have unrestricted cash in accounts maintained in the name of Borrower with Bank and Bank's Affiliates, in an amount equal to the lesser of (i) one hundred percent (100.0%) of the Dollar value of all account balances of Borrower, its Subsidiaries, and any Guarantor, wherever located, and (ii) one hundred ten percent (110.0%) of the outstanding Obligations of Borrower to Bank (the "**Account Threshold**")."

2.3.Section 5.15 (Cash Collateralization). The Loan Agreement is amended by inserting the following new Section 5.15 to appear immediately following Section 5.14 thereof:

" **5.15 Cash Collateralization**. If, at any time, the outstanding Obligations with respect to the Term Loan Advances exceeds $25,000,000.00, then Borrower shall maintain, during such time, Liquidity in an amount of at least $100,000,000.00 (the "**Required Liquidity Amount**"). If, at any time during which Borrower is required to maintain the Required Liquidity Amount, Borrower fails to maintain the Required Liquidity Amount (which failure in and of itself is not a Default or an Event of Default) (the "**Trigger Event**"), Borrower shall promptly (and in any event, within three (3) Business Days) deposit into the SVB Operating Account, unrestricted and unencumbered (other than Liens in favor of Bank arising under the Loan Documents) cash in an amount greater than or equal to the amount of all outstanding Obligations with respect to the Term Loan Advances in excess of $25,000,000.00 (the "**Cash Collateralized Amount**"), to secure such outstanding

Obligations (a "**Cash Collateralization**") (and the failure to so deposit the Cash Collateralized Amount into the SVB Operating Account within three (3) Business Days shall be an Event of Default). Borrower hereby authorizes and directs Bank to transfer to the Collateral Money Market Account an amount equal to the Cash Collateralized Amount at any time after the occurrence of the Trigger Event and (i) after Borrower deposits the Cash Collateralized Amount into the SVB Operating Account or (ii) if Borrower fails to effect a Cash Collateralization as required under this Section 5.15. If, at any time following the occurrence of a Trigger Event, (x) the outstanding Obligations with respect to the Term Loan Advances are less than or equal to $25,000,000.00 or (y) the Borrower maintains the Required Liquidity Amount, Bank shall promptly (and in any event, within three (3) Business Days) transfer all amounts then on deposit in the Collateral Money Market Account to an unrestricted operating account in the name of Borrower maintained at Bank."

2.4.Section 12.2 (Definitions). The following terms and their respective definitions appearing in Section 12.2 are hereby amended in their entirety and replaced with the following:

" "**Loan Documents**" are, collectively, this Agreement and any schedules, exhibits, certificates, notices, and any other documents related to this Agreement, the Perfection Certificate, the Cash Pledge Agreement, any Control Agreement, any Bank Services Agreement, any subordination agreement, any note, or notes or guaranties executed by Borrower or any Guarantor, landlord waivers and consents, bailee waivers and consents, and any other present or future agreement by Borrower and/or any Guarantor with or for the benefit of Bank in connection with this Agreement or Bank Services, all as amended, restated, or otherwise modified in accordance with the terms thereof."

" "**Prepayment Fee**" shall be an additional fee, payable to Bank, with respect to each Term Loan Advance, in an amount equal to:

(a) for a prepayment of the Term Loan Advances made on or prior to the first (1st) anniversary of the First Amendment Effective Date, 3.0% of the then-outstanding principal amount of the Term Loan Advances being prepaid immediately prior to the date of such prepayment;

(b) for a prepayment of the Term Loan Advances made after the first (1st) anniversary of the First Amendment Effective Date, but on or prior to the second (2nd) anniversary of the First Amendment Effective Date, 2.0% of the then-outstanding principal amount of the Term Loan Advances being prepaid immediately prior to the date of such prepayment; and

(c) for a prepayment of the Term Loan Advances made after the second (2nd) anniversary of the First Amendment Effective Date, but prior to the Term Loan Maturity Date, 1.00% of the then-outstanding principal amount of the Term Loan Advances immediately prior to the date of such prepayment.

Notwithstanding the foregoing, provided no Event of Default has occurred and is continuing, the Prepayment Fee shall be waived by Bank, if Bank closes on the refinance and redocumentation of the Term Loan Advances (in its sole and absolute discretion) prior to the Term Loan Maturity Date."

2.5.Section 12.2 (Definitions). The following new terms and their respective definitions are hereby inserted to appear alphabetically in Section 12.2 thereof:

" "**Cash Collateralization**" is defined in Section 5.15."

" "**Cash Collateralized Amount**" is defined in Section 5.15."

" "**Cash Pledge Agreement**" is that certain Bank Services Cash Pledge Agreement dated as of the First Amendment Effective Date executed by Borrower in favor of Bank."

" "**Collateral Money Market Account**" means a segregated collateral money market account of Borrower maintained with Bank, which is subject to the Cash Pledge Agreement."

" "**Draw Period C**" is set forth on Schedule I hereto."

" "**First Amendment Effective Date**" is June 28, 2024."

" "**Liquidity**" means unrestricted and unencumbered (other than Liens in favor of Bank arising under the Loan Documents) cash and Cash Equivalents in accounts in the name of Borrower maintained with Bank or Bank's Affiliates or maintained with financial institutions other than Bank which are subject to a Control Agreement in favor of Bank."

" "**Required Liquidity Amount**" is defined in Section 5.15."

" "**SVB Operating Account**" is Borrower's account ending in 523 maintained at Bank."

" "**Term C Loan Advance**" and "**Term C Loan Advances**" are each defined in Section 1.1(a) hereof."

" "**Term C Loan Availability Amount**" is set forth on Schedule I hereto."

" "**Trigger Event**" is defined in Section 5.15."

2.6.Schedule I (Loan Terms). Schedule I to the Loan Agreement is amended in its entirety and replaced with the Schedule I appearing on Schedule 1 attached hereto.

2.7.Exhibit A (Compliance Statement). The Compliance Statement appearing on Schedule 2 hereto is hereby inserted to appear as Exhibit A to the Loan Agreement.

3.Limitation of Amendments.

3.1. The amendments set forth in Section 2 above are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right or remedy which Bank may now have or may have in the future under or in connection with any Loan Document.

3.2. This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, except as herein amended, are hereby ratified and confirmed and shall remain in full force and effect.

4.Representations and Warranties. To induce Bank to enter into this Amendment, Borrower hereby represents and warrants to Bank as follows:

4.1. Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (b) no Event of Default has occurred and is continuing;

4.2. Borrower has the power and authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

4.3. The organizational documents of Borrower delivered to Bank on the Effective Date remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;

4.4. The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, have been duly authorized;

4.5. The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not and will not contravene (a) any law or regulation binding on or affecting Borrower, (b) any contractual restriction with a Person binding on Borrower, (c) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (d) the organizational documents of Borrower;

4.6. The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or

validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower, except as already has been obtained or made; and

4.7. This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

5.Updated Perfection Certificate. Borrower has delivered an updated Perfection Certificate in connection with this Amendment (the "**Updated Perfection Certificate**") dated as of the date hereof, which Updated Perfection Certificate shall supersede in all respects that certain Perfection Certificate dated as of September 5, 2023. Borrower agrees that all references in the Loan Agreement to "Perfection Certificate" shall hereinafter be deemed to be a reference to the Updated Perfection Certificate.

6.Post-Closing Condition.

6.1. Within 10 Business Days after the First Amendment Effective Date, Borrower shall deliver to Bank, a Certificate of Good Standing/Foreign Qualification from the Commonwealth of Massachusetts in form and substance satisfactory to Bank.

6.2. Within 30 days after the First Amendment Effective Date, Borrower shall deliver to Bank, each in form and substance satisfactory to Bank, evidence satisfactory to Bank that the insurance policies and endorsements required by Section 5.5 of the Loan Agreement are in full force and effect, together with appropriate evidence showing lender loss payable and additional insured clauses or endorsements in favor of Bank.

7.Fees and Expenses. Borrower shall reimburse Bank for all unreimbursed Bank Expenses, including without limitation, all legal fees and expenses incurred in connection with this Amendment.

8.Governing Law. This Amendment shall be governed and construed in accordance with the laws of the State of California, without giving effect to conflicts of laws principles.

9.Integration. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents.

10.Counterparts. This Amendment may be executed in any number of counterparts and all of such counterparts taken together shall be deemed to constitute one and the same instrument. Each party hereto may execute this Amendment by electronic means and recognizes and accepts the use of electronic signatures and records by any other party hereto in connection with the execution and storage hereof.

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

11.Effectiveness. This Amendment shall be deemed effective upon the due execution and delivery to Bank of this Amendment by each party hereto.

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed as of the date first written above.

BANK	**BORROWER**
FIRST-CITIZENS BANK & TRUST COMPANY	OLEMA PHARMACEUTICALS, INC.
By: /s/ Peter Sletteland	
Name: Peter Sletteland	By: /s/ Shane Kovacs
Title: Managing Director	Name: Shane Kovacs
	Title: Chief Operating and Financial Officer

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Schedule 1

SCHEDULE I
LSA PROVISIONS

LSA Section	LSA Provision
1.1(a) – Term Loan – Availability	Each Term Loan Advance must be in an amount equal to at least $5,000,000.00. After repayment, no Term Loan Advance (or any portion thereof) may be reborrowed.
1.1(b) – Term Loan – Repayment	Commencing on August 1, 2026 and continuing on each Payment Date thereafter, Borrower shall repay each Term Loan Advance in (i) 24 consecutive equal monthly installments of principal, plus (ii) monthly payments of accrued interest at the rate set forth in Section 1.2(b)(i).
1.2(a) – Interest Payments – Term Loan Advances	Interest on the principal amount of each Term Loan Advance is payable in arrears monthly (A) on each Payment Date commencing on the first Payment Date following the Funding Date of each such Term Loan Advance, (B) on the date of any prepayment and (C) on the Term Loan Maturity Date.
1.2(b)(i) – Interest Rate – Term Loan Advances	The outstanding principal amount of any Term Loan Advance shall accrue interest at a floating rate per annum equal to the greater of (1) 8.0% and (2) the Prime Rate, which interest shall be payable in accordance with Section 1.2(a).
1.2(e) – Interest Computation	Interest shall be computed on the basis of the actual number of days elapsed and a 360-day year.
12.2 – "Draw Period A"	"**Draw Period A**" is the period commencing as of the Effective Date and ending on June 30, 2025.
12.2 – "Draw Period B"	"**Draw Period B**" is the period commencing upon the occurrence of the Term B Milestone Event and ending on July 31, 2026.
12.2 – "Draw Period C"	"**Draw Period C**" is the period commencing upon the occurrence of the Term C Milestone Event and ending on July 31, 2026.
12.2 – "Effective Date"	"**Effective Date**" is September 5, 2023.
12.2 – "Payment Date"	"**Payment Date**" is the first (1st) calendar day of each month.
12.2 – "Prime Rate"	"**Prime Rate**" is the rate of interest per annum from time to time published in the money rates section of The Wall Street Journal or any successor publication thereto as the "prime rate" then in effect; provided that if such rate of interest, as set forth from time to time in the money rates section of The Wall Street Journal, becomes unavailable for any reason as determined by Bank, the "Prime Rate" shall mean the rate of interest per annum announced by Bank as its prime rate in effect at its principal office in the State of California (such Bank announced Prime Rate not being intended to be the lowest rate of interest charged by Bank in connection with extensions of credit to debtors); provided that, in the event such rate of interest is less than zero percent (0.0%) per annum, such rate shall be deemed to be zero percent (0.0%) per annum for purposes of this Agreement.
12.2 – "Term A Loan Availability Amount"	"**Term A Loan Availability Amount**" is an aggregate principal amount equal to $25,000,000.00.

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12.2 – "Term B Loan Availability Amount"	"**Term B Loan Availability Amount**" is an aggregate principal amount equal to $25,000,000.00.
12.2 – "Term B Milestone Event"	**"Term B Milestone Event**" means Borrower has delivered to Bank, on or prior to July 31, 2026, evidence satisfactory to Bank in its sole and absolute discretion, that Borrower has obtained the resources necessary to execute a proposed first-line pivotal Phase 3 clinical trial of palazestrant in combination with ribociclib [*].
12.2 – "Term C Loan Availability Amount"	"**Term C Loan Availability Amount**" is an aggregate principal amount equal to $50,000,000.00.
12.2 – "Term C Milestone Event"	"**Term C Milestone Event**" occurs if and when (if ever), at any time prior to July 31, 2026, Bank confirms in writing that: (a) Borrower has requested and Bank has made all available Term A Loan Advances and Term B Loan Advances, (b) Bank has received all necessary internal and credit approvals to make the Term C Loan Advances in an amount not to exceed the Term C Availability Amount, (c) no Event of Default exists at the time the initial Term C Loan Advance is requested or would exist as a result of the initial Term C Loan Advance, and (d) Bank has provided written approval in its sole discretion that the initial Term C Loan Advance shall occur.
12.2 – "Term Loan Maturity Date"	"**Term Loan Maturity Date**" is July 1, 2028.

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Schedule 2

EXHIBIT A
COMPLIANCE STATEMENT

TO: Silicon Valley Bank, a division of First-Citizens Bank & Trust Company Date: _
FROM: OLEMA PHARMACEUTICALS, INC.

Under the terms and conditions of the Loan and Security Agreement between Borrower and Bank (as amended, modified, supplemented and/or restated from time to time, the "**Agreement**"), Borrower is in complete compliance for the period ending _____ with all required covenants except as noted below. Attached are the required documents evidencing such compliance, setting forth calculations prepared in accordance with GAAP consistently applied from one period to the next except as explained in an accompanying letter or footnotes. Capitalized terms used but not otherwise defined herein shall have the meanings given them in the Agreement.

Please indicate compliance status by circling Yes/No under "Complies" column.

Reporting Covenants	Required	Complies
Compliance Statement	Monthly within 30 days (except for the months ending March 31, June 30, September 30, and December 31)	Yes No
Quarterly Compliance Statement	Q1, Q2, and Q3 within 45 days	Yes No
10-Q Report	Within 45 days of Q1, Q2, and Q3	Yes No
10-K Report and Annual financial statements (CPA Audited)	FYE within 90 days	Yes No
Board approved projections	FYE within 30 days and as amended/updated	Yes No
Filed 10-Q, 10-K and 8-K	Within 10 days after filing with SEC	Yes No

Section 5.7(a) (Operating Accounts):

a) Account balances in the name of Borrower at Bank and Bank's Affiliates: $_____

b) Dollar Equivalent value of Borrower's, its Subsidiaries' and any Guarantor's cash, wherever located: $_____

c) Outstanding Obligations under the Agreement: $_____

d) Is Line A at least 110% of Line C:

a. Yes, in compliance: _____

b. No, not in compliance: _____

e) If not in compliance with Line D: is Line A equal to Line B?

a. Yes, in compliance: _____

b. No, not in compliance: _____

f) If in compliance with Line D, is Line A greater than or equal to 50% (excluding the account balance maintained in the Permitted JPM Operating Account)of Line B

a. Yes, in compliance: _____

b. No, not in compliance: _____

5.15 Cash Collateralization:

a) Outstandings: Obligations with respect to the Term Loan Advances equals: $_____ (if greater than $25,000,000, proceed to (B) and (C) below)

b) Liquidity: Unrestricted and unencumbered (other than Liens in favor of Bank arising under the Loan Documents) cash and Cash Equivalents in accounts in the name of Borrower maintained with Bank or Bank's Affiliates or maintained with financial institutions other than Bank which are subject to a Control Agreement in favor of Bank: $_____

c) Cash Collateralization: Is Line B less than $100,000,000.00:

a. No, no Trigger Event or Cash Collateralization requirement: _____

b. Yes, Trigger Event has occurred, and Cash Collateralization is required: _____

The following are the exceptions with respect to the statements above: (If no exceptions exist, state "No exceptions to note.")

The following bank account information set forth on Schedule 1 attached hereto is true and correct as of the date of this Compliance Statement:

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Schedule 1

BANK ACCOUNT REPORT

Under the terms and conditions of the Loan and Security Agreement between Borrower and Bank (as amended, modified, supplemented and/or restated from time to time, the "**Agreement**"), Borrower confirms that the below disclosed accounts represent all depository accounts and securities accounts presently open in the name of each Borrower, Subsidiary, or Guarantor, as applicable.

Each new account that has been opened since delivery of the previous Compliance Certificate is designated below with a "*".

	Depository AC #	Financial Institution	Account Type (Depository / Securities)	Last Month Ending Account Balance	Purpose of Account
BORROWER Name/Address:					
1					
2					
3					
4					
5					
6					
7					
SUBSIDIARY Name/Address					
1					
2					
3					
4					
5					
6					
7					
GUARANTOR Name/Address					
1					
2					
3					
4					
5					
6					
7					

EXHIBIT 10.2

OLEMA PHARMACEUTICALS, INC.
AMENDED AND RESTATED
NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

Each member of the Board of Directors (the "***Board***") of Olema Pharmaceuticals, Inc. (the "***Company***") who is not also serving as an employee of the Company or any of its subsidiaries (each such member, an "***Eligible Director***") will receive the compensation described in this Non-Employee Director Compensation Policy (this "***Policy***"). An Eligible Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash is to be paid or equity awards are to be granted, as the case may be. This Policy shall be effective as of the date the registration statement for the Company's initial public offering of common stock is declared effective (the "***Effective Date***") and may be amended at any time in the sole discretion of the Board, or by the Compensation Committee of the Board at the recommendation of the Board.

Annual Cash Compensation

The annual cash compensation amount set forth below is payable to Eligible Directors in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred. The first quarterly installment payable after the Effective Date to Eligible Directors in office as of the Effective Date will be pro-rated for the partial quarter measured from the Effective Date to the last day of the quarter. Further, if an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, his or her first quarterly installment will be pro-rated based on days served in the applicable quarter. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:
   a. All Eligible Directors: $40,000
   b. Non-executive chairperson of the Board: $70,000 (inclusive of Annual Board Service Retainer)

2. Annual Committee Member (non-Chair) Service Retainer:
   a. Member of the Audit Committee: $8,000
   b. Member of the Compensation Committee: $6,000
   c. Member of the Nominating and Corporate Governance Committee: $5,000

3. Annual Committee Chair Service Retainer (inclusive of Committee Member Service Retainer):
   a. Chairperson of the Audit Committee: $18,750
   b. Chairperson of the Compensation Committee: $12,000
   c. Chairperson of the Nominating and Corporate Governance Committee: $10,000

The Company will also reimburse each of the Eligible Directors for his or her travel expenses incurred in connection with his or her attendance at Board and committee meetings. Such reimbursements shall be paid on the same date as the annual cash fees are paid.

Equity Compensation

The equity compensation set forth below will be granted under the Company's 2020 Equity Incentive Plan, as the same may be amended or restated from time to time (the "***Plan***"). Capitalized terms used below not otherwise defined in this Policy shall have the meanings given to them in the Plan All stock

options granted under this Policy will be nonstatutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying common stock on the date of grant, a term of 10 years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan), and subject to all the terms, conditions and limits set forth in the Plan and the applicable award agreement. For the avoidance of doubt, the share numbers in this Policy shall be subject to adjustment as provided in the Plan.

1. Initial Grant: For each Eligible Director who is first elected or appointed to the Board following the Effective Date, on the date of such Eligible Director's initial election or appointment to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option to purchase a number of shares of the Company's common stock equal to 23,000 shares of the Company's common stock. The shares subject to each such stock option will vest monthly over a three-year period, subject to the Eligible Director's Continuous Service on each vesting date, and will vest in full upon a Change in Control, subject to the Eligible Director's Continuous Service through such date. In addition, on the date of such Eligible Director's initial election or appointment to the Board (or, if such date is not a market trading day, the first market trading day thereafter), such Eligible Director shall automatically, and without further action by the Board or Compensation Committee of the Board, be granted an additional stock option representing the Annual Grant (as defined below) he or she would have received had he or she been elected to the Board at the prior annual meeting of stockholders, pro-rated for the partial year of service. For example, if an Eligible Director is appointed to the Board on December 1, 2021, and the Company's last annual meeting were on June 1, 2021, the Eligible Director would receive an additional pro-rated grant for 50% of the Annual Grant, with such pro-rated grant vesting upon the earlier of (a) the first anniversary of the date the Annual Grants to non-employee directors were last made and (b) the next annual meeting of stockholders. Such additional option will vest in full upon a Change in Control, subject to the Eligible Director's Continuous Service through such date.

2. Annual Grant: On the first market trading day after each annual stockholders meeting of the Company, each Eligible Director who continues to serve as a member of the Board through and following such stockholders meeting will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option to purchase 23,000 shares of the Company's common stock (the "***Annual Grant***"). The shares subject to each such stock option will vest monthly over a one-year period following the grant date, and will vest in full on the date of the Company's next annual stockholders meeting if such stock option is not otherwise fully vested by such date, subject to the Eligible Director's Continuous Service on each vesting date. Such option will vest in full upon a Change in Control, subject to the Eligible Director's Continuous Service through such date.

Compensation Limits

Notwithstanding anything to the contrary in this Policy, all compensation payable under this Policy will be subject to any limits on the maximum amount of Eligible Director compensation set forth in the Plan, as in effect from time to time.

Approved by the Board of Directors: April 4, 2024

Exhibit 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

I, Sean Bohen, certify that:

1.I have reviewed this Quarterly Report on Form 10-Q of Olema Pharmaceuticals, Inc.;

2.Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3.Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4.The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a)Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b)Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c)Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d)Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5.The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a)All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b)Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 6, 2024

By: /s/ Sean Bohen
Sean Bohen
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 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

I, Shane Kovacs, certify that:

1.I have reviewed this Quarterly Report on Form 10-Q of Olema Pharmaceuticals, Inc.;

2.Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3.Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4.The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a)Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b)Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c)Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d)Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5.The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a)All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b)Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 6, 2024

By: /s/ Shane Kovacs
Shane Kovacs
Chief Operating and Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Sean Bohen, M.D. Ph.D., Chief Executive Officer of Olema Pharmaceuticals, Inc. (the "Company"), and Shane Kovacs, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

(1)The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2024, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

(2)The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 6, 2024

By: /s/ Sean Bohen
Sean Bohen
President and Chief Executive Officer

Date: August 6, 2024

By: /s/ Shane Kovacs
Shane Kovacs
Chief Operating and Financial Officer

"This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Olema Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing."