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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2026

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 November 5, 2026, the number of outstanding shares of the Registrant's common stock was 87,606,263. This number does not include 13,594,149 shares of common stock issuable upon the exercise of pre-funded warrants (which are immediately exercisable at an exercise price of $0.0001 per share of common stock, subject to beneficial ownership limitations) (See Notes 2 and 12 to Registrant's condensed consolidated financial statements).

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements.

Olema Pharmaceuticals, Inc.

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

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 47,522	$ 48,301
Marketable securities	366,249	457,136
Prepaid expenses and other current assets	9,654	10,015
Total current assets	423,425	515,452
Operating lease right-of-use assets	349	1,146
Other assets and long-term deposits	17,296	16,832
Total assets	$ 441,070	$ 533,430
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,209	$ 9,253
Operating lease liabilities, current	356	1,124
Other current liabilities	67,668	41,425
Total current liabilities	69,233	51,802
Operating lease liabilities, net of current portion	—	69
Long-term borrowing	3,000	3,000
Total liabilities	72,233	54,871
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of September 30, 2026 and December 31, 2025; no shares issued and outstanding as of September 30, 2026 and December 31, 2025.	—	—
Common stock, $0.0001 par value; 490,000,000 shares authorized as of September 30, 2026 and December 31, 2025; 87,537,824 and 81,376,449 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively.	8	8
Additional paid-in capital	1,157,865	1,075,487
Accumulated other comprehensive (loss)/income	(1,591)	621
Accumulated deficit	(787,445)	(597,557)
Total stockholders' equity	368,837	478,559
Total liabilities and stockholders' equity	$ 441,070	$ 533,430

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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 67,598	$ 39,951	$ 174,615	$ 114,477
General and administrative	9,927	5,926	28,075	14,137
Total operating expenses	77,525	45,877	202,690	128,614
Loss from operations	(77,525)	(45,877)	(202,690)	(128,614)
Other income:				
Interest income	4,054	3,648	13,337	12,214
Other (loss)/income	(128)	12	(535)	10
Total other income	3,926	3,660	12,802	12,224
Net loss	$ (73,599)	$ (42,217)	$ (189,888)	$ (116,390)
Net loss per share, basic and diluted	$ (0.73)	$ (0.49)	$ (1.89)	$ (1.36)
Weighted average shares used to compute net loss per share, basic and diluted	101,092,706	85,732,221	100,609,258	85,553,078

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Net loss	$ (73,599)	$ (42,217)	$ (189,888)	$ (116,390)
Other comprehensive (loss)/income:				
Net unrealized (loss)/gain on marketable securities	(644)	212	(2,212)	383
Total comprehensive loss	$ (74,243)	$ (42,005)	$ (192,100)	$ (116,007)

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 September 30, 2026					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income/(Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at June 30, 2026	87,452,166	$ 8	$ 1,145,349	$ (947)	$ (713,846)	$ 430,564
Stock-based compensation expense, including employee stock purchase plan expense	—	—	12,082	—	—	12,082
Exercise of stock options	85,658	—	434	—	—	434
Net unrealized loss on marketable securities	—	—	—	(644)	—	(644)
Net loss	—	—	—	—	(73,599)	(73,599)
Balances at September 30, 2026	87,537,824	$ 8	$ 1,157,865	$ (1,591)	$ (787,445)	$ 368,837

	Nine Months Ended September 30, 2026					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income/(Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2025	81,376,449	$ 8	$ 1,075,487	$ 621	$ (597,557)	$ 478,559
Exchange of pre-funded warrants for common stock shares	3,500,000	—	—	—	—	—
Issuance of shares under at-the-market offering, net of issuance costs of $40	1,712,739	—	41,918	—	—	41,918
Stock-based compensation expense, including employee stock purchase plan expense	—	—	35,133	—	—	35,133
Exercise of stock options	885,858	—	4,675	—	—	4,675
Issuance of shares under employee stock purchase plan	62,778	—	652	—	—	652
Net unrealized loss on marketable securities	—	—	—	(2,212)	—	(2,212)
Net loss	—	—	—	—	(189,888)	(189,888)
Balances at September 30, 2026	87,537,824	$ 8	$ 1,157,865	$ (1,591)	$ (787,445)	$ 368,837

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 September 30, 2025					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at June 30, 2025	68,627,886	$ 7	$ 854,194	$ 314	$ (509,279)	$ 345,236
Stock-based compensation expense, including employee stock purchase plan expense	—	—	4,250	—	—	4,250
Exercise of stock options	24,844	—	7	—	—	7
Net unrealized loss on marketable securities	—	—	—	212	—	212
Net loss	—	—	—	—	(42,217)	(42,217)
Balances at September 30, 2025	68,652,730	$ 7	$ 858,451	$ 526	$ (551,496)	$ 307,488

	Nine Months Ended September 30, 2025					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2024	74,312,608	$ 7	$ 843,920	$ 143	$ (435,106)	$ 408,964
Stock-based compensation expense, including employee stock purchase plan expense	—	—	13,320	—	—	13,320
Issuance of shares under employee stock purchase plan	206,609	—	748	—	—	748
Exercise of stock options	203,513	—	477	—	—	477
Issuance cost associated with private equity placement	—	—	(14)	—	—	(14)
Exchange of common stock shares for pre-funded warrants	(6,070,000)	—	—	—	—	—
Net unrealized gain on marketable securities	—	—	—	383	—	383
Net loss	—	—	—	—	(116,390)	(116,390)
Balances at September 30, 2025	68,652,730	$ 7	$ 858,451	$ 526	$ (551,496)	$ 307,488

See accompanying notes to the condensed consolidated financial statements.

Olema Pharmaceuticals, Inc.

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

	Nine Months Ended September 30,	
	2026	**2025**
Cash flows from operating activities:		
Net loss	$ (189,888)	$ (116,390)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	315	303
Non-cash lease expense	899	875
Non-cash interest income on marketable securities	(3,367)	(5,135)
Stock-based compensation expense, including employee stock purchase plan expense	35,133	13,320
Loss on sale of equipment	98	—
Change in assets and liabilities:		
Prepaid expenses and other current assets	1,675	(960)
Other assets and long-term deposits	(716)	(5,649)
Accounts payable	(8,044)	(1,175)
Other current liabilities	25,839	7,353
Operating lease liabilities	(939)	(931)
Net cash used in operating activities	(138,995)	(108,389)
Cash flows from investing activities:		
Purchase of equipment	(1,121)	—
Proceeds from sale of equipment	50	—
Maturities of marketable securities	260,995	253,794
Purchases of marketable securities	(168,953)	(247,370)
Net cash provided by investing activities	90,971	6,424
Cash flows from financing activities:		
Issuance of shares under at-the-market offering, net of issuance costs of $40	41,918	—
Issuance costs for shares issued under private placement	—	(6,514)
Proceeds from exercise of stock options	4,675	511
Proceeds from borrowings under Credit Facility	—	3,000
Proceeds from issuance of common stock under employee stock purchase plan	652	748
Net cash provided by / (used in) financing activities	47,245	(2,255)
Net change in cash and cash equivalents	(779)	(104,220)
Cash and cash equivalents at beginning of period	48,301	139,480
Cash and cash equivalents at end of period	$ 47,522	$ 35,260
Supplemental disclosure of non-cash financing activity		
Exchange of common stock for pre-funded warrants	$ —	$ 29,379
Right-of-use asset obtained in exchange for operating lease liabilities	55	896
Purchases of property and equipment included in accrued expenses	404	—

See accompanying notes to the unaudited 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 breast cancer and beyond. 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 OP-3136, a potent KAT6 inhibitor.

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, incorporated on January 6, 2021 under the laws of Australia, and Olema Oncology International Limited, incorporated on December 11, 2025 under the laws of Ireland, are wholly-owned subsidiaries 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 late-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 nonclinical 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 $413.8 million of cash, cash equivalents, and marketable securities at September 30, 2026, in addition to the available balance under the Loan and Security Agreement dated as of September 5, 2023 (the “Original Loan Agreement”), 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 (the "First Amendment"), as further amended by the Second Amendment to Loan and Security Agreement, dated June 27, 2025 (the "Second Amendment"), as further amended by the Third Amendment to Loan and Security Agreement, dated January 11, 2026 (the "Third Amendment"), and as further amended by the Fourth Amendment to Loan and Security Agreement, dated July 1, 2026 (the "Fourth Amendment" and, collectively with the First Amendment, Second Amendment, Third Amendment and the Original Loan Agreement, the "Loan Agreement"). See Note 11, "Long-term Borrowing" for further 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.

Follow-on Public Offering

On November 19, 2025, the Company completed a follow-on public offering pursuant to which it issued and sold 11,500,000 shares of its common stock at a public offering price of $19.00 per share, including 1,500,000 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares, resulting in aggregate net proceeds of $204.8 million, after deducting underwriting discounts and commissions and estimated offering costs.

Private Placement

On November 29, 2024, the Company entered into a securities purchase agreement for a private placement of (i) 19,928,875 shares of the Company's common stock at a price of $9.08 per share and (ii) pre-funded warrants to purchase up to an aggregate of 7,604,163 shares of the Company's common stock at a price of $9.0799 per pre-funded warrant, which represents the per share purchase price of the Company's common stock sold in the private placement less the $0.0001 per share exercise price for each pre-funded warrant to selected institutional and accredited investors (the "2024 Private Placement"). The aggregate gross proceeds for the 2024 Private Placement were approximately $250.0 million. After deducting offering expenses related to the 2024 Private Placement of approximately $13.0 million, the net proceeds to the Company from the 2024 Private Placement were approximately $237.0 million.

Warrant Exchanges

On November 29, 2024 and January 10, 2025, the Company entered into exchange agreements with certain investors and issued to such investors pre-funded warrants to purchase up to 3,420,000 and 6,070,000 shares of the Company's common stock, respectively, in exchange for an equivalent number of shares of the Company's common stock previously outstanding and held by such investors (the "Exchange Transactions"). The pre-funded warrants were issued without registration under the Securities Act of 1933, as amended (the "Securities Act"), in reliance on the exemption from registration contained in Section 3(a)(9) of the Securities Act. Refer to Note 12, "Pre-funded Warrants" for further details.

At-The-Market Offering

On January 5, 2024, the Company entered into a sales agreement (the "2024 Sales Agreement") with Cowen and Company, LLC ("Cowen and Company") as sales agent, pursuant to which the Company was permitted to offer and sell, from time to time, shares of its common stock, having an aggregate offering price of up to $150.0 million (the "2024 ATM Shares"). The sales of the 2024 ATM Shares were made by an "at-the-market" ("ATM") equity offering as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended ("Securities Act"). The Company agreed to pay Cowen and Company a commission of up to 3.0% of the aggregate gross proceeds from any 2024 ATM Shares sold by Cowen and Company. During the year ended December 31, 2024, the Company issued 1,772,278 shares of the Company's common stock under the 2024 Sales Agreement at a weighted-average price of $13.19 for net proceeds of $22.8 million after deducting related issuance costs.

On January 6, 2025, the Company entered into a sales agreement (the "2025 Sales Agreement") with TD Securities (USA) LLC, ("TD Cowen") as sales agent, pursuant to which the Company was permitted to sell, from time to time, shares of the Company's common stock, having an aggregate offering price of up to $150.0 million (the "2025 ATM Shares"). The 2025 Sales Agreement replaced the prior 2024 Sales Agreement. The sales of the 2025 ATM Shares would be made by any method permitted that is deemed to be an 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. The Company agreed to pay TD Cowen a commission of up to 3.0% of the aggregate gross proceeds from any 2025 ATM Shares sold by TD Cowen. On December 11, 2025, the Company entered into Amendment No. 1 to the 2025 Sales Agreement, which increased the maximum aggregate offering price under the 2025 Sales Agreement to $200.0 million. During the nine months ended September 30, 2026, the Company issued 1,712,739 shares of the Company's common stock under the 2025 Sales Agreement at a weighted-average price of $24.92 for net proceeds of $41.9 million after deducting related issuance costs.

Impact of Geopolitical and Macroeconomic Events

Global economic and business activities continue to face widespread uncertainty related to the geopolitical and macroeconomic environment, generally, including economic uncertainty, market volatility, labor shortages, recent and changing tariff policy announcements (including related legal challenges), tariffs, trade tensions and retaliatory measures by other countries, supply chain disruptions, military conflicts, as well as any related political or economic responses and counter-responses or otherwise by various global actors, inflationary pressures, monetary supply shifts, increased recession risk, and related financial instability. 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 subsidiaries, Olema Oncology Australia Pty Ltd and Olema Oncology International Limited. All intercompany balances and transactions have been eliminated upon consolidation. Certain prior period amounts have been reclassified to conform to the current period presentation. Such reclassifications had no effect on the Company's previously reported financial position, results of operations, comprehensive loss, or cash flows.

Unaudited Interim Financial Information

The accompanying interim condensed consolidated financial statements are unaudited. They 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 nine-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, 2026, or for any other future annual or interim period. The condensed consolidated balance sheet as of December 31, 2025 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 16, 2026 (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 equity awards. 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 September 30, 2026, and December 31, 2025. Cash and cash equivalents primarily consisted of cash on deposit with U.S. banks, including the Company's bank accounts for its foreign subsidiaries, denominated in U.S. dollars and foreign currencies, 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 credit losses, 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 credit losses in accordance with ASC 326, *Financial Instruments—Credit Losses*. 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; 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 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

Under Accounting Standards Update ("ASU") 2016-02, Leases, Topic 842, ("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 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. Refer to Note 9, "Leases" for further details.

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 nonclinical 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 either prepaid expenses and other current assets or other assets and long-term deposits. 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.

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.

Internal-Use Software

The Company capitalizes certain costs incurred for the development and implementation of computer software for internal use. These costs generally relate to the implementation of the third-party developed software for the Company's clinical development purposes. The Company capitalizes these costs when it is determined that it is probable that the project will be completed and the software will be used to perform the function intended, and the preliminary project stage is completed. Capitalized internal-use software development and implementation costs are included in Other assets and long-term deposits within the consolidated balance sheets. Capitalized implementation costs are amortized on a straight-line basis over the estimated useful lives of five years. Costs related to the preliminary project stage, post-implementation, training and maintenance are expensed as incurred.

Comprehensive Loss

Comprehensive loss includes net loss and other comprehensive (loss) gain for each period presented. Other comprehensive (loss) gain represents net unrealized (loss) gain on marketable securities.

Stock-Based Compensation

The Company recognizes stock compensation in accordance with Accounting Standards Codification ("ASC") 718, *Compensation — Stock Compensation* ("ASC 718"). Stock-based compensation cost, including grants of stock options and restricted stock units issued under the Company's equity incentive plans, and the 2020 Employee Stock Purchase Plan (the "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.

The Company estimates the fair value of stock options with time-based vesting on the date of grant utilizing the Black-Scholes option-pricing model, which requires the input of subjective assumptions, including (i) the expected volatility of its stock, (ii) the expected term of the award, (iii) the risk-free interest rate, and (iv) expected dividends. The Company estimates the volatility of its stock based on a weighted average of the volatility of the Company's stock price and that of its peers. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available. Starting from the period ended September 30, 2026, the Company uses its historical information of stock option exercises to estimate the expected term of the award. Previously, the Company used the simplified approach to estimate the expected term of the award as the mid-point between the vesting date and the contractual term of the option. The risk-free rates for period within the expected term of the option are based on the U.S. Treasury yield curve during the period the options were granted. The expected dividend yield of zero is based on the fact that the Company has never paid dividends and does not expect to pay any cash dividends in the foreseeable future. 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. 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.

The Company measures the fair value of restricted stock units ("RSU"s) based on the closing price of the Company's common stock on the grant date. Stock-based compensation expense for RSUs is recognized on a straight-line basis over the vesting term.

Equity Awards with Market and Service Conditions

The fair value and derived service period of performance-based awards granted with market and service conditions are estimated on the grant date using a Monte Carlo simulation model. A Monte Carlo simulation model requires inputs such as the risk-free interest rate, expected award term, expected share dilution and expected share price volatility. These inputs, which are subjective and generally require significant judgment, are unique to each award based on the best available information at the grant date. For such awards, stock-based compensation expense is recognized on a straight-line basis over the derived service period of each tranche. Stock-based compensation expense will continue to be recognized over the derived service period regardless of whether the awards' market-based vesting terms have been satisfied, so long as the requisite service is rendered by the grantee.

Foreign Currency Transactions

The functional currency of Olema Oncology Australia Pty Ltd and Olema Oncology International Limited, the Company’s wholly-owned subsidiaries, 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 condensed 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.

Pre-funded Warrants

The Company issued pre-funded warrants in connection with the 2024 Private Placement and the Exchange Transactions executed in November 2024 and January 2025. Refer to Note 12, "Pre-funded Warrants" for further details.

The Company accounts for the pre-funded warrants as a freestanding equity-linked financial instrument that met the criteria for equity classification pursuant to ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480"), and ASC 815, *Derivatives and Hedging* ("ASC 815"). Accordingly, the Company recorded the pre-funded warrants as a component of stockholders' equity within additional paid-in capital. The Company valued the pre-funded warrants at issuance, concluding that their sales price approximated their fair value. The pre-funded warrants are immediately exercisable at an exercise price of $0.0001 per share of the Company's common stock, subject to beneficial ownership limitations. Exercise of the pre-funded warrants is virtually assured because the underlying common shares will be issued for nominal cash consideration or at an exercise price of $0.0001 per share. All necessary conditions for issuance of the underlying common shares were met when the pre-funded warrants were issued, and as such, related pre-funded warrants shares were included in the denominator for both the basic and diluted earnings per share calculations.

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, including the pre-funded warrants shares. 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 the pre-funded warrants shares and potential dilutive common shares. For purpose of this calculation, outstanding stock options and contingently issuable common stock related to 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.

Segment Reporting

The Company operates as a single operating and reportable segment. The Company's Chief Executive Officer serves as the chief operating decision maker ("CODM"). The CODM reviews the Company's financial information on a consolidated basis for purposes of assessing financial performance, making operating decisions, and allocating resources. The CODM uses consolidated net loss, as determined in accordance with U.S. GAAP and reported in the Company's condensed consolidated statements of operations, as the measure of segment profit or loss, primarily by monitoring actual results compared to forecasted results, as well as by reviewing year-over-year results. The measure of segment assets is reported in the Company's condensed consolidated balance sheet as total consolidated assets. In assessing segment performance and allocating resources, the CODM also reviews consolidated functional expenses, including research and development and general and administrative expenses. Other segment items included in consolidated net loss is primarily interest income, which is reflected in the consolidated statements of operations and comprehensive loss.

Recent Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, *Disaggregation of Income Statement Expenses*, which requires public business entities to provide enhanced disclosures about specific expense categories in both interim and annual financial statements. The new standard requires entities to disclose in tabular format certain categories of expenses, including purchases of inventory, employee compensation, depreciation, intangible asset amortization, and other specified expense categories, along with a qualitative description of amounts remaining in relevant expense captions. The objective of this ASU is to provide investors with more detailed information to better assess an entity's performance and future cash flow prospects. ASU 2024-03 is effective for public business entities for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact of this standard on its consolidated financial statement disclosures.

In September 2025, the FASB issued ASU 2025-06, *Targeted Improvements to the Accounting for Internal-Use Software*, which modernizes the accounting guidance for costs associated with developing or obtaining internal-use software. The ASU eliminates the previous stage-based model (preliminary project stage, application development stage, and post-implementation stage) and replaces it with a principles-based approach that better aligns with modern software development practices, including agile and iterative methodologies. Under the new guidance, entities may begin capitalizing internal-use software development costs when (1) management has authorized and committed to funding the software project, and (2) it is probable that the project will be completed and the software will be used to perform the function intended. The ASU also supersedes the separate guidance on website development costs and incorporates it into the internal-use software framework. ASU 2025-06 is effective for all entities for annual reporting periods beginning after December 15, 2027, and interim reporting periods within those annual reporting periods. Early adoption is permitted as the beginning of an annual reporting period. The Company is currently evaluating the impact of this standard on its consolidated financial statements.

On December 8, 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270): Narrow Scope Improvements*, which is intended to improve the navigability of the guidance in ASC 270, *Interim Reporting* ("ASC 270") and clarify when it applies. Under the amendments, an entity is subject to ASC 270 if it provides interim financial statements and notes in accordance with GAAP. The ASU also addresses the form and content of such financial statements, adds lists to ASC 270 of the interim disclosures required by all other Codification topics, and establishes a principle under which an entity must disclose events since the end of the last annual reporting period that have a material impact on the entity. ASU 2025-11 is not intended to change the fundamental nature of interim reporting or expand or reduce current interim disclosure requirements. ASU 2025-11 is effective for all public business entities for interim reporting periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact of this standard on its consolidated financial statements.

In December 2025, the FASB issued ASU 2025-12, *Codification Improvements*, which clarifies, corrects errors in and makes other improvements to various Topics in the Accounting Standards Codification. The amendments are effective for annual reporting periods beginning after December 15, 2026, including interim periods within those annual periods, with early adoption permitted. The Company has evaluated the amendments and does not expect the adoption to have a material impact on the condensed consolidated financial statements or related disclosures.

The Company continues to monitor new accounting pronouncements issued by the FASB and does not believe that any pronouncements issued but not yet adopted as of the date of this report will have a material impact on the Company's consolidated financial statements.

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.

As of September 30, 2026, and December 31, 2025, the fair value of the Company's financial assets that are measured at fair value on a recurring basis, which consist of cash equivalents and marketable securities classified as available-for-sale, are categorized in the table below based upon the lowest level of significant input to the valuations:

	September 30, 2026			
(in thousands)	Level 1	Level 2	Level 3	Total
Financial Assets				
Cash	$ 18,485	$ —	$ —	$ 18,485
Money market funds	29,123	—	—	29,123
Commercial paper	—	63,169	—	63,169
Corporate bonds	—	86,140	—	86,140
U.S. government treasury bills	174,289	—	—	174,289
Government-sponsored enterprise securities	—	42,651	—	42,651
Total	$ 221,897	$ 191,960	$ —	$ 413,857

(in thousands)	December 31, 2025 Level 1	Level 2	Level 3	Total
Financial Assets				
Cash	$ 16,007	$ —	$ —	$ 16,007
Money market funds	30,866	—	—	30,866
Commercial paper	—	102,193	—	102,193
Corporate bonds	—	81,607		81,607
U.S. government treasury bills	233,938	—	—	233,938
Government-sponsored enterprise securities	—	41,029	—	41,029
Total	$ 280,811	$ 224,829	$ —	$ 505,640

The amortized cost and fair value of cash equivalents and investments as of September 30, 2026 and December 31, 2025 were as follows:

(in thousands)	September 30, 2026 Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Financial Assets				
Cash and cash equivalents	$ 47,608	$ —	$ —	$ 47,608
Short-term marketable securities (<12 months to maturity)	311,165	3	(949)	310,219
Long-term marketable securities (>12 months to maturity)	56,652	—	(622)	56,030
Total	$ 415,425	$ 3	$ (1,571)	$ 413,857

(in thousands)	December 31, 2025 Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Financial Assets				
Cash and cash equivalents	$ 48,503	$ —	$ —	$ 48,503
Short-term marketable securities (<12 months to maturity)	300,243	501	(12)	300,732
Long-term marketable securities (>12 months to maturity)	156,273	160	(28)	156,405
Total	$ 505,019	$ 661	$ (40)	$ 505,640

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 credit losses in accordance with ASC 326. 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 September 30, 2026. The Company did not recognize any credit-related impairment losses or an allowance for credit losses on its available-for-sale marketable securities during the nine months ended September 30, 2026 and 2025.

As of September 30, 2026, all of the Company's cash and cash equivalents primarily consisted of cash on deposit with U.S. banks denominated in U.S. dollars, Euro and Australian dollars, and investments in interest-bearing money market funds.

4. Prepaid Expenses and Other Current Assets

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

	September 30, 2026	December 31, 2025
Interest receivable	$ 3,105	$ 3,137
Prepaid G&A related costs	2,829	501
Prepaid clinical development costs	2,264	3,190
Prepaid insurance	952	1,049
Value added tax receivable	269	1,297
Other prepaid and current assets[1]	235	841
Total	$ 9,654	$ 10,015

[1] Other current assets as of December 31, 2025 included a $0.5 million tax refund receivable from the Australian Taxation Office related to the 2025 calendar year, which was received in February 2026.

5. Other Assets and Long-Term Deposits

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

	September 30, 2026	December 31, 2025
Clinical development project deposits	$ 14,303	$ 15,202
Property and equipment, net	1,648	274
Internal-use software	729	892
Office lease deposits	616	464
Total	$ 17,296	$ 16,832

6. Accrued and Other Current Liabilities

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

	September 30, 2026	December 31, 2025
Accrued research and development related costs	$ 57,307	$ 29,286
Accrued employee bonuses	6,813	8,253
Accrued corporate related costs	2,968	2,737
Accrued payroll related costs	580	1,149
Total	$ 67,668	$ 41,425

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. In December 2024, the Compensation Committee of the Board approved an increase of an additional 3,000,000 shares of common stock reserved for issuance under the 2022 Inducement Plan, which increase was made effective as of January 1, 2025. In September 2026, the Compensation Committee of the Board approved an increase of an additional 3,000,000 shares of common stock reserved for issuance under the 2022 Inducement Plan, which increase was made effective as of September 1, 2026. 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. Prior to the third quarter of 2026, the Company estimated the expected term of stock options with service-based vesting conditions using the simplified method for awards that qualify as "plain-vanilla" options due to lack of sufficient historical exercise data. Beginning the third quarter of 2026, the Company estimates the expected term based on its historical stock options exercise data. 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. The 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:

	September 30, 2026	September 30, 2025
Risk-free interest rate	4.07%	4.08%
Expected term (in years)	5.90	6.04
Expected volatility	87.09%	78.10%
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	Aggregate Intrinsic Value
			(in years)	(in thousands)
Outstanding as of December 31, 2025	14,429,539	$ 8.89	7.40	$ 235,660
Granted	5,538,239	20.47	—	—
Exercised[1]	(890,265)	5.35	—	—
Forfeited/Cancelled	(778,672)	10.50	—	—
Outstanding as of September 30, 2026	18,298,841	$ 12.50	7.30	$ 30,987
Options vested and exercisable as of September 30, 2026	9,321,399	$ 9.79	5.69	$ 20,953
Options expected to vest as of September 30, 2026	8,977,442	$ 15.32	8.97	$ 10,034

[1] Exercised amount includes 4,407 shares withheld for taxes and net exercise transactions.

Restricted Stock Units

During the nine months ended September 30, 2026, the Company granted RSUs to non-executive employees under the 2020 Plan.

The following table summarizes the RSU activity during the nine months ended September 30, 2026:

	Number of Shares	Weighted Average Fair Value
Outstanding as of December 31, 2025	—	$ —
Granted	411,845	25.65
Vested	—	—
Forfeited	(44,330)	25.65
Outstanding as of September 30, 2026	367,515	$ 25.65
Expected to vest as of September 30, 2026	367,515	$ 25.65

Market-based Stock Options

On February 2, 2026, the Company granted stock options with market and service conditions under the 2020 Plan. These awards vest upon the achievement of specified stock price targets, subject to continued service. The estimated grant date fair value of the market-based options was approximately $13.5 million. **The Company estimated the grant-date fair value of these awards using a Monte Carlo simulation model incorporating the following assumptions:**

Risk-free interest rate	4.00%
Expected term (in years)	6.95
Expected volatility	103.54%
Expected dividend yield	—

The following table summarizes the market-based stock options activity during the nine months ended September 30, 2026:

	Number of Shares	Grant Date Fair Value	Weighted Average Remaining Contractual Term (in years)
Outstanding as of December 31, 2025	—	$ —	—
Granted	668,750	25.65	9.35
Exercised	—	—	—
Forfeited	—	—	—
Outstanding as of September 30, 2026	668,750	$ 25.65	9.35

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 $0.1 million and $0.1 million for the three-month periods ended September 30, 2026 and 2025, and $0.8 million and $0.5 million for the nine-month periods ended September 30, 2026 and 2025, 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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 7,693	$ 2,582	$ 23,155	$ 9,592
General and administrative	4,389	1,668	11,978	3,728
Total	$ 12,082	$ 4,250	$ 35,133	$ 13,320

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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Numerator:				
Net loss	$ (73,599)	$ (42,217)	$ (189,888)	$ (116,390)
Denominator:				
Weighted average shares used to compute net loss per share, basic and diluted *	101,092,706	85,732,221	100,609,258	85,553,078
Net loss per share, basic and diluted	$ (0.73)	$ (0.49)	$ (1.89)	$ (1.36)

* Reflects the weighted average effect of the pre-funded warrants on the calculation of basic and diluted net loss per share.

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:

	September 30,	
	2026	2025
Options to purchase common stock	18,298,841	15,486,430
Unvested market-based stock options outstanding	668,750	—
Unvested restricted stock units outstanding	367,515	—
Employee stock purchase plan contingently issuable	33,081	52,567
	19,368,187	15,538,997

9. Leases

The Company leases certain of its facilities under non-cancellable operating leases expiring at various dates into 2027.

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 was for a period of five years commencing approximately February 1, 2021 and ending January 31, 2026. In April 2025, the Company exercised its option to extend the lease term by an additional year, resulting in a revised expiration date of January 31, 2027. The modification was accounted under ASC 842, resulting in a remeasurement of the lease liability and a corresponding $0.8 million increase to the ROU asset. The incremental borrowing rate was also updated as part of the remeasurement. 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. No additional security deposit was paid in connection with the amendment.

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 was for a period of two years commencing on September 5, 2023 and ending December 31, 2025. In June 2025, the Company entered into a First Amendment to the Dropbox Sublease Agreement and exercised its option to extend the lease term by an additional year, resulting in a revised expiration date of December 31, 2026. The modification was accounted under ASC 842, resulting in a remeasurement of the lease liability and a corresponding $0.1 million increase to the ROU asset. The incremental borrowing rate was also updated as part of the remeasurement. In January 2026, the Company entered into a Second Amendment to the Dropbox Sublease Agreement, which did not have a material economic impact on the existing lease.

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, at inception of the lease. In January 2026, the Company entered into a First Amendment to the Cambridge Lease Agreement, which extended the lease term by six months, from September 15, 2026 through March 14, 2027, and granted the Company an early termination option. The First Amendment was accounted for as a lease modification under ASC 842. The related operating lease liability and ROU asset were remeasured using an updated incremental borrowing rate as of the modification date, resulting in an increase of less than $0.1 million to the lease liability and a corresponding increase to the ROU asset.

On April 27, 2026, the Company entered into a lease agreement with KR Oyster Point II, LLC to lease an aggregate of approximately 38,176 square feet of office and laboratory space to serve as the Company's new corporate headquarters (the “Oyster Point Lease Agreement”), consisting of approximately 25,048 square feet on the fourth floor (“Phase I”) and approximately 13,128 square feet on the fifth floor (“Phase II”). The Oyster Point Lease Agreement has an initial term of seven years, with commencement upon the earlier of the Company’s first use of the applicable space or the landlord’s delivery of possession of such space in the condition required under the lease. Aggregate base rent over the initial term, net of rent abatement, is approximately $18.5 million, consisting of approximately $12.4 million related to Phase I and approximately $6.1 million related to Phase II. The Company is also required to pay its pro rata share of operating expenses, taxes, assessments and fees. The Company paid to the landlord a security deposit of $0.4 million. The Oyster Point Lease Agreement provides the Company with a one-time option to terminate the lease at the end of the 60th full calendar month of the initial term, subject to, among other requirements, payment of a termination fee of approximately $1.7 million. The Company also has an option to extend the lease term for one additional five-year period and a right of first offer to lease certain additional space. The Company will account for the Oyster Point Lease Agreement under ASC 842 at the respective lease commencement dates. As of September 30, 2026, the lease had not commenced and, accordingly, no right-of-use asset or lease liability had been recognized. The lease subsequently commenced on October 14, 2026, upon receipt of the certificate of occupancy from the applicable governmental authority.

On June 2, 2026, the Company entered into a lease agreement with ARE-MA Region No. 75, LLC to lease an aggregate of approximately 16,653 square feet of office space in Watertown, Massachusetts (the "Watertown Lease"). The Watertown Lease Agreement is for a period of 44 months commencing on the target commencement date of January 15, 2027. Aggregate base rent over the initial term, net of rent abatement, is approximately $1.2 million. According to the terms of the Watertown Lease Agreement, the Company paid to the landlord a security deposit of $0.1 million. The Company is required to pay monthly rent and common area charges. The Company will account for the Watertown Lease under ASC 842 at the respective lease commencement date. As of September 30, 2026, the Watertown Lease had not commenced and, accordingly, no right-of-use asset or lease liability had been recognized.

The following table summarizes total lease expense during the three and nine months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Straight-line operating lease expense	$ 302	$ 300	$ 903	$ 875
Variable lease expense	91	100	304	284
Short-term lease expense	15	—	28	—
Total operating lease expense	$ 408	$ 400	$ 1,235	$ 1,159

The following table summarizes supplemental cash flow information during the three and nine months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Cash paid for amounts included measurement of lease liabilities:				
Operating cash flows from operating leases	$ 313	$ 312	$ 938	$ 931
Lease liability arising from obtaining a right-of-use-asset	$ —	$ —	$ 55	$ 896

The following table summarizes the Company's future minimum lease payments and reconciliation of lease liabilities as of September 30, 2026 (in thousands):

Year Ending December 31,	
2026 (From October 2026)	$ 290
2027	69
Total future minimum lease payments	359
Less: Interest	3
Total lease liabilities at present value	356
Lease liabilities, current	356
Lease liabilities, non-current	$ —

The following table summarizes the lease term and discount rate as of September 30, 2026 and 2025:

	September 30,	
	2026	2025
Weighted-average remaining lease term (years)	0.31	1.26
Weighted-average discount rate	8.50%	9.00%

10. Commitments and Contingencies

2024 Novartis Agreement

On November 29, 2024, the Company entered into a Clinical Trial Collaboration and Supply Agreement (the "2024 Novartis Agreement") with Novartis Pharma AG (collectively, with affiliated entities, "Novartis"). Pursuant to the 2024 Novartis Agreement, Novartis is providing the Company with ribociclib drug supply for the Company's ongoing Phase 3 OPERA-02 trial of palazestrant in combination with ribociclib in ER+/HER2- frontline advanced or metastatic breast cancer (the "OPERA-02 trial").

Under the 2024 Novartis Agreement, the Company supplies (including manufacturing, packaging and labeling) palazestrant and letrozole for the OPERA-02 trial. Novartis manufactures and supplies (including primary packaging) the Company with a specified amount of ribociclib, which amount is expected to be sufficient for the OPERA-02 trial. The parties have granted 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. Any inventions developed in the performance of the clinical studies for the combined therapies (other than those specific to each component study drug) are jointly owned by the parties. Except as otherwise specified below, the 2024 Novartis Agreement does not grant any right of first negotiation to participate in future clinical trials, and each party retains all rights and ability to evaluate their respective compounds in any studies or clinical trials, either as a monotherapy or in combination with any other product or compound, in any therapeutic area. The parties retain their independent rights to commercialize their respective therapies both alone and with third parties.

The Company granted Novartis a right of first negotiation with respect to (a) the grant to any person or entity any right, license or sublicense to exploit palazestrant, in any field or territory, other than to third party service providers, or (b) the sale or other transfer to any person or entity of palazestrant and any related assets (each referred to herein as an "Olema Compound Transaction"). If the Company desires to or does, at any time, (a) solicit or entertain any third party proposal or indication of interest with respect to an Olema Compound Transaction, or (b) negotiate (including in response to any proposal or indication of interest received by the Company), enter into or perform under, in each case, any written definitive agreement with a third party with respect to or that contemplates an Olema Compound Transaction, then the Company must provide written notice to Novartis regarding such Olema Compound Transaction, along with certain other specified information. Novartis will have 30 days after receipt of such notice to elect to enter into exclusive good faith negotiations with respect to such Olema Compound Transaction for a period of up to 120 days.

If the Company's board of directors (or a duly authorized board committee) determines that the Company should pursue or explore a change of control of the Company or sale of all or substantially all of its assets (an "Olema Change of Control"), other than in response to an unsolicited bona fide acquisition proposal (a "Proposed Sale"), the Company must promptly notify Novartis of such determination. In the event Novartis elects to engage in negotiations with the Company in respect of such Proposed Sale, then from the date such notice is given until 45 days after the later of (a) the date on which the foregoing notice is given to Novartis, (b) the date on which Novartis is given notice that a data room has been populated as required by the 2024 Novartis Agreement, and (c) entry by the Company and Novartis into a customary nondisclosure agreement, Novartis will have the exclusive right (but no obligation) to conduct due diligence on the Company and its business and negotiate with the Company and its representatives the definitive terms and conditions of the Proposed Sale.

If the Company or its affiliates receive an unsolicited bona fide acquisition proposal from a third party, the Company must promptly notify its board of directors (or a duly authorized board committee) of the receipt thereof and request that they consider the merits of such acquisition proposal. If, after such consideration, the Company's board of directors (or authorized committee) authorizes the Company to engage in negotiations with regard to such acquisition proposal, then the Company must notify Novartis in writing within 24 hours of receipt of such authorization. To the extent possible in light of any confidentiality obligations, such notice must include a summary of the key structural, non-financial terms of such acquisition proposal.

In the event of an Olema Compound Transaction or Olema Change of Control involving a third party other than Novartis (the first to occur, a "Repayment Trigger Event"), the Company must promptly pay, or procure the payment of, the Repayment Amount (as defined below) to Novartis. Notwithstanding the foregoing, if the 2024 Novartis Agreement is terminated as a result of certain patient safety issues, lack of product efficacy, regulatory issues or clinical hold issues prior to the consummation of the Olema Compound Transaction or Olema Change of Control, then the Company shall not be obligated to pay the Repayment Amount unless (a) the Olema Change of Control or Olema Compound Transaction occurs after such termination and (b) prior to the fifth anniversary of such Olema Change of Control or Olema Compound Transaction (as applicable), the Company or its affiliates (or the applicable acquirer, successor, licensee or optionholder of the Company or its affiliates) enrolls a subject in any clinical study involving the combination of palazestrant and ribociclib (the "Olema Combination") or submits any filing with any regulatory authority relating to the Olema Combination. The "Repayment Amount" is the proportion of approximately $275 million that is represented by the number of units of ribociclib actually supplied to the Company under the 2024 Novartis Agreement as of immediately prior to the Repayment Trigger Event as compared to the total number of units that could be supplied under the 2024 Novartis Agreement.

The foregoing rights of first negotiation, first offer and notice and repayment obligations remain in effect until the first to occur of: (a) the date that is 120 days after filing of the New Drug Application for the Olema Combination, (b) one year after any expiration or termination of the 2024 Novartis Agreement, and (c) such time as the 2024 Novartis Agreement is terminated by the Company due to Novartis' material breach. However, in the event the 2024 Novartis Agreement is terminated due to certain patient safety issues, lack of product efficacy, regulatory issues or clinical hold issues prior to the consummation of an Olema Change of Control or Olema Compound Transaction, then the Repayment Obligation shall survive until the fifth anniversary of such Olema Change of Control or Olema Compound Transaction (as applicable) or, if payment of the Repayment Amount is required, until the next business day after the Repayment Amount has been received by Novartis.

The 2024 Novartis Agreement will terminate on the fifth anniversary of the date on which the first dose of palazestrant is administered to the first study subject. Either party may terminate the 2024 Novartis Agreement for the uncured material breach or insolvency of the other party, for failure to comply with certain anti-corruption obligations, in the event of a change of control 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 studies for the combined therapies due to the existence of a material safety issue, if the parties jointly decide that the Olema Combination is not achieving sufficiently superior levels of efficacy, if any regulatory authority action prevents a party (or the letrozole supplier) from supplying its product, in the event of an unresolved force majeure event, or in certain circumstances for an unresolved clinical hold with respect to ribociclib, palazestrant or letrozole (or the combination of ribociclib and palazestrant or ribociclib and letrozole). In addition, Novartis may terminate the 2024 Novartis Agreement if the Company had failed to commence the OPERA-02 trial on or prior to March 31, 2026 or if the Company consummates an Olema Compound Transaction. The Company may terminate the 2024 Novartis Agreement if the Company terminates the OPERA-02 trial other than due to a material safety issue, efficacy issue, regulatory action, or upon a clinical hold.

Costs incurred in connection with the 2024 Novartis Agreement are included in research and development expenses in the accompanying condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2026 and 2025.

2020 Novartis Agreement

On July 22, 2020, the Company entered into a non-exclusive clinical collaboration and supply agreement with Novartis. On January 13, 2022, the Company entered into an 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") to the amended and restated clinical collaboration and supply agreement (as amended, the "2020 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 study of palazestrant in patients with metastatic estrogen receptor-positive breast cancer. The Novartis Amendment, among other things, expanded the Company's clinical collaboration with Novartis, increasing the size of the ongoing Phase 1/2 study testing palazestrant in combination with ribociclib to approximately 60 patients. 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 2020 Novartis Agreement will terminate upon completion of all activities outlined in the development plan and the relevant protocols. Either party may terminate the 2020 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 2020 Novartis Agreement if certain disputes between the parties are not resolved after following the applicable dispute resolution procedures, and the Company may terminate the 2020 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 2020 Novartis Agreement are included in research and development expenses in the accompanying condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2026 and 2025, with any reimbursable costs from Novartis reflected as a reduction of such expenses. The Company had previously incurred the full agreed-upon reimbursement amount.

2025 Pfizer Agreement

In September 2025, the Company announced that it entered into a non-exclusive clinical trial collaboration and supply agreement with Pfizer Inc. (“Pfizer”) (the “2025 Pfizer Agreement”), to evaluate the safety and tolerability of palazestrant in combination with Pfizer’s proprietary investigative selective CDK4 inhibitor atirmociclib in patients with metastatic ER+, HER2- breast cancer in a Phase 1b/2 clinical trial. Under the terms of the 2025 Pfizer Agreement, the Company is responsible for conducting the clinical trial for the combined therapies and Pfizer is responsible for supplying atirmociclib 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 atirmociclib 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. Pfizer is responsible for manufacturing and delivering to us atirmociclib in such quantities as reasonably needed for the clinical trials for the combined therapies.

The 2025 Pfizer Agreement will terminate upon completion of all activities outlined in the study plan and the relevant protocols. Either party may terminate the 2025 Pfizer Agreement for the uncured material breach 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 atirmociclib or palazestrant. In addition, Pfizer may terminate the 2025 Pfizer Agreement if Pfizer reasonably and in good faith believes that atirmociclib is being used in an unsafe manner, and either party may terminate the 2025 Pfizer Agreement if either party determines to discontinue clinical development for medical, scientific, legal or other reasons.

The 2025 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 with the 2025 Pfizer Agreement are included in research and development expenses in the accompanying condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2026.

2020 Pfizer Agreement

In November 2020, the Company entered into a non-exclusive clinical trial agreement with 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 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 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 with the Pfizer Agreement are included in research and development expenses in the accompanying condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2026 and 2025.

2026 Bayer Agreement

In May 2026, the Company entered into a clinical trial collaboration and supply agreement with Bayer Consumer Care AG ("Bayer") (the "2026 Bayer Agreement") to evaluate, in a Phase 1b/2 study, the safety, tolerability, and preliminary anti-tumor activity of OP-3136 in combination with NUBEQA® (darolutamide), Bayer's androgen receptor inhibitor, in approximately 36 patients with metastatic castration-resistant prostate cancer. The clinical trial is expected to initiate in the fourth quarter of 2026.

Under the 2026 Bayer Agreement, Bayer will supply NUBEQA® for use in the clinical trial, and the Company will sponsor and conduct the study. The parties have granted each other a non-exclusive, royalty-free license under certain of their respective patent rights solely to the extent reasonably necessary to conduct the clinical trial and related research and development activities under the collaboration. Inventions and data generated through the conduct of the clinical trial relating to the combined use of OP-3136 and NUBEQA® will be jointly owned by the parties. The Company is responsible for manufacturing, packaging and labeling OP-3136, as well as packaging and labeling NUBEQA®, while Bayer is responsible for manufacturing and supplying NUBEQA® in quantities reasonably required for the clinical trial.

The 2026 Bayer Agreement may be terminated by either party under certain circumstances, including for an uncured material breach, patient safety concerns, clinically significant drug-drug interactions, certain regulatory actions, or a decision to discontinue development of the applicable compound or combination for medical, scientific or legal reasons. In addition, Bayer may terminate the 2026 Bayer Agreement if it reasonably believes NUBEQA® is being used unsafely in the clinical trial or if its underlying supply agreement terminates and it is no longer able to supply NUBEQA®. Upon expiration or termination of the 2026 Bayer Agreement, the Company is required to return or destroy any unused NUBEQA® in accordance with Bayer's instructions.

The 2026 Bayer 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. There were no costs incurred in connection with the 2026 Bayer Agreement for the three and nine months ended September 30, 2026.

2022 License Agreement with Aurigene

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 Aurigene Agreement, Aurigene has provided to us an exclusive license to Aurigene's rights to patents and applications related to our KAT6 inhibitor program. We co-own with Aurigene a patent-family related to OP-3136.

Under the terms of the Aurigene Agreement, Aurigene provided to the Company an exclusive license to its portfolio of novel small molecule inhibitors of the target. Financial terms of the Aurigene Agreement included an $8.0 million upfront payment for rights to the pre-existing Aurigene KAT6 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 royalties on product sales, if any, ranging from mid-single digits to the low double digits as a percentage of such sales. During the research term, the Company contributes funding to Aurigene to facilitate Aurigene's ongoing discovery efforts. The Company and Aurigene 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.

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. As of September 30, 2026, the Company has incurred $23 million in upfront and clinical development milestone payments under the Aurigene Agreement.

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 September 30, 2026, 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 September 30, 2026, the Company had not incurred any material costs as a result of such indemnifications.

11. Long-term Borrowing

On September 5, 2023, the Company entered into the Original Loan Agreement by and between the Company and the Bank. 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"), of which $25.0 million became available upon the closing of a private placement and the issuance of our common stock to selected institutional and accredited investors pursuant to a securities purchase agreement in September 2023 ("Term Loan A"),

and the remaining $25.0 million could have been made available upon approval of the Bank in its discretion. The Original Credit Facility was scheduled to mature on August 1, 2027 (the "Original Maturity Date").

On June 28, 2024, the Company entered into the First Amendment, which, among other things, (i) increased 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 the Term Loan A of $25.0 million was immediately available, an additional $25.0 million became available upon the Company achieving certain milestones related to the execution of a first line pivotal Phase 3 clinical trial of palazestrant in combination with ribociclib ("Term Loan B"), and an additional $50.0 million which may be made available upon the approval of the Bank in its discretion ("Term Loan C"), and (ii) extended the Original Maturity Date to July 1, 2028.

On June 27, 2025, the Company entered into the Second Amendment, which, among other things, (i) decreased the interest rate to a floating rate equal to the greater of 6.0% or the prime rate, and (ii) extended the draw period of the Term Loan A to January 15, 2026.

On January 11, 2026, the Company entered into the Third Amendment, which, among other things, (i) extended the draw period of Term Loan A to January 31, 2027, (ii) extended the draw period of Term Loan B to January 31, 2027, (iii) extended the draw period of Term Loan C to January 31, 2027, and (iv) extended the maturity date to January 1, 2029 ("Maturity Date"). Based on the occurrence of specified (a) development milestones related to the pivotal Phase 3 OPERA-01 clinical trial of palazestrant or (b) receipt of proceeds from capital financing, the draw period of Term Loan B and Term Loan C may be further extended to July 31, 2027, and the Maturity Date may be further extended to July 1, 2029.

On July 1, 2026, the Company entered into the Fourth Amendment, which, among other things, added Olema Oncology International Limited as a secured guarantor under the Loan Agreement.

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 greater of (i) 6.0% 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.

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.

As of September 30, 2026, the Company had drawn $3.0 million from the Credit Facility which was recorded at cost and presented as long-term borrowing on the consolidated balance sheet. The interest expense amounted to $0.2 million for the nine months ended September 30, 2026, which was included in other income on the condensed consolidated statement of operations and comprehensive loss. As of September 30, 2026, the carrying amount of the borrowing approximated fair value, as the interest rate is variable and resets periodically based on market rates.

12. Pre-Funded Warrants

The Company accounts for the pre-funded warrants as a freestanding equity-linked financial instrument that met the criteria for equity classification pursuant to ASC 480 and ASC 815. Accordingly, the Company recorded the pre-funded warrants as a component of stockholders' equity within additional paid-in capital. During the nine months ended September 30, 2026, partial pre-funded warrants were exercised in exchange for 3.5 million shares of the Company's common shares. The following table summarizes the pre-funded warrants issued and outstanding as of September 30, 2026:

Issued Year	Expiration Date	Exercise Price	Number of Warrants Outstanding
2024 (Private Placement)	None	$ 0.0001	4,104,149
2024 (Warrant Exchange Agreement)	None	0.0001	3,420,000
2025 (Warrant Exchange Agreement)	None	0.0001	6,070,000
			13,594,149

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 (Quarterly Report), 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, 2025, filed with the U.S. Securities and Exchange Commission (SEC), on March 16, 2026 (Annual Report).

This Quarterly Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (Securities Act) and Section 21E of the Securities Exchange Act of 1934, as amended (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. 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

Olema is a clinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of next-generation targeted therapies for breast cancer and beyond. 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, is a novel, orally-available small molecule with dual activity as both a complete estrogen receptor (ER) antagonist (CERAN) and selective ER degrader (SERD), currently being investigated in patients with recurrent, locally advanced or metastatic ER positive (ER+), human epidermal growth factor receptor 2 negative (HER2-) breast cancer. In pre-clinical models, palazestrant binds and completely blocks ER-driven transcriptional activity in both wild-type and mutant forms of ER+ metastatic breast cancer (MBC). In clinical studies across more than 400 patients, palazestrant has demonstrated strong anti-tumor activity, attractive pharmacokinetics and prolonged drug exposure, favorable tolerability, and combinability with cyclin dependent kinase 4/6 (CDK4/6) inhibitors with no significant drug-drug interaction. Based on the clinical results we have achieved to date, we are advancing palazestrant through late-stage clinical development both as a monotherapy and in combination with other targeted agents.

In November 2023, we initiated OPERA-01, our pivotal Phase 3 clinical trial of palazestrant as a monotherapy in second/third-line ER+/HER2- MBC. We have completed enrollment and anticipate top-line results for this trial in the first quarter of 2027, expect to submit the new drug application (NDA) in 2027, and, if successful, anticipate potential U.S. Food and Drug Administration (FDA) approval and commercial launch in 2028.

In addition, we are investigating palazestrant in multiple Phase 1/2 studies in combination with CDK4/6 inhibitors (palbociclib or ribociclib), a phosphatidylinositol-3-kinase alpha (PI3Ka) inhibitor (alpelisib), with an mTOR inhibitor (everolimus), and a CDK4 inhibitor (atirmociclib). The Phase 1b/2 study investigating palazestrant in combination with atirmociclib has completed enrollment and we expect to present initial data at the San Antonio Breast Cancer Symposium (SABCS) in December 2026. We also expect to present the first clinical data from the Phase 1b/2 study evaluating palazestrant in combination with everolimus at the same conference.

In October 2025, at the European Society for Medical Oncology (ESMO) Annual Meeting, we presented updated results from the ongoing Phase 1b/2 clinical trial of palazestrant in combination with ribociclib in patients with ER+/HER2- MBC. These data further support our thesis that palazestrant possesses key characteristics to make it a potential backbone endocrine therapy of preference for ER+/HER2- breast cancer, while also supporting the ongoing pivotal Phase 3 clinical trial of palazestrant in combination with ribociclib in frontline ER+/HER2- MBC, called OPERA-02. The execution of OPERA-02 is supported by our clinical trial collaboration and supply agreement with Novartis Pharma AG (Novartis), which was announced in December 2024. Under the terms of the agreement, Novartis is providing Olema with ribociclib drug supply for the OPERA-02 trial, which initiated in 2025 and is currently enrolling patients.

Our second product candidate in clinical development, called OP-3136, is a novel, orally-available small molecule that potently and selectively inhibits KAT6, an epigenetic target that is dysregulated in breast and other cancers. The Investigational New Drug (IND) application for OP-3136 was cleared by the FDA in late 2024 and the Phase 1b/2 study is enrolling patients. In nonclinical studies, OP-3136 has demonstrated anti-tumor activity in prostate, ovarian, and non-small cell lung cancer models and is combinable and synergistic with endocrine therapies, including palazestrant and CDK4/6 inhibitors, in breast cancer models. At the American Association for Cancer Research (AACR) Annual Meeting in April 2026, we presented additional nonclinical data demonstrating that OP-3136, in combination with palazestrant, exhibited synergistic anti-tumor activity in ER+/HER2- breast cancer models driven by suppression of cell-cycle and estrogen receptor-driven oncogenic signaling.

At the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting, we presented encouraging initial monotherapy data from Part 1A of the OP-3136 Phase 1b/2 study. These data showed OP-3136 monotherapy was well-tolerated, with no dose-limiting toxicities observed and no discontinuations due to treatment-related adverse events, and showed evidence of anti-tumor activity across multiple solid tumor types at multiple dose levels. We anticipate presenting initial combination data from the Phase 1b/2 clinical study of OP-3136 in combination with fulvestrant at SABCS in December 2026 and additional combination data in mid-2027. Furthermore, in May 2026, we announced a clinical trial collaboration and supply agreement with Bayer Consumer Care AG (Bayer) to evaluate the safety, tolerability, and preliminary anti-tumor activity OP-3136 in combination with NUBEQA® (darolutamide), Bayer's androgen receptor inhibitor, in approximately 36 patients with metastatic castration-resistant prostate cancer. This new combination arm in the ongoing OP-3136 Phase 1b/2 study is expected to initiate in the fourth quarter of 2026.

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 nonclinical 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 nonclinical 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 $189.9 million and $116.4 million for the nine months ended September 30, 2026 and 2025, 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 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 September 30, 2026, we had an accumulated deficit of $787.4 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+/HER2- breast cancer;
- continue to enroll patients in the Phase 1b/2 study 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 in 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, geopolitical uncertainty, 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 revenue or positive cash flow from operating activities.

Global economic and business activities continue to face widespread uncertainty due to the geopolitical and macroeconomic environment, generally, including economic and geopolitical uncertainty, market volatility, labor shortages, evolving trade and tariffs policies, including related legal challenges, trade tensions, and retaliatory measures by other countries, supply chain disruptions, military conflicts, as well as any related political or economic responses or counter-responses by various global actors, inflationary pressures, monetary supply shifts, increased recession risk, and related financial instability. 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 nonclinical 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 efforts and nonclinical and clinical development of our product candidates, including under agreements with third parties, such as consultants and contract research organizations (CROs);
- costs of manufacturing products for use in our nonclinical studies and clinical trials, including payments to contract manufacturing organizations (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 nonclinical 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;
- allocated facility-related costs, which include rent, depreciation and maintenance expenses, and other operating costs; and
- costs to continue to enhance our clinical, operational, financial, and information systems to support ongoing product development and planned future commercialization efforts.

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 as well as additional team members hired to support ongoing product development and planned future commercialization efforts.

We expense research and development expenses in the periods in which they are incurred. Costs for certain activities, such as manufacturing, nonclinical 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 nonclinical program, but we do not allocate personnel costs, other internal costs, or external consultant costs to specific product candidates or nonclinical 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 future product candidates we may develop into and through nonclinical 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 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 future product candidates we may develop. Clinical and nonclinical 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 nonclinical 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 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 nonclinical and clinical development programs are subject to numerous uncertainties in timing and cost to completion. The duration, costs, and timing of nonclinical studies, clinical trials, and development of our product candidates will depend on a variety of factors, including:

- the timing and progress of nonclinical and clinical development activities;
- the number and scope of nonclinical 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 expenses, for personnel in executive, finance, accounting, business development, communications and investor relations, commercialization, legal, human resources, information technology (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 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, the potential future commercialization of our product candidates, 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, such as cybersecurity monitoring, legal, 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 the standards applicable to companies listed on a national securities exchange, as well as additional insurance expenses and other administrative and professional services.

Total other income

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

Results of operations

Comparison of the three months ended September 30, 2026 and 2025

The following table summarizes our results of operations for the three months ended September 30, 2026 and 2025:

	Three Months Ended September 30,			
	2026	2025	$ Change	% Change
	(in thousands)			
Operating expenses:				
Research and development	$ 67,598	$ 39,951	$ 27,647	69%
General and administrative	9,927	5,926	4,001	68%
Total operating expenses	77,525	45,877	31,648	69%
Loss from operations	(77,525)	(45,877)	(31,648)	69%
Other income:				
Interest income	4,054	3,648	406	11%
Other (loss) income	(128)	12	(140)	*NM
Total other income	3,926	3,660	266	7%
Net loss	$ (73,599)	$ (42,217)	$ (31,382)	74%

*NM - Not Meaningful

Research and development expenses

The following table summarizes our research and development expenses by functional area for the three months ended September 30, 2026 and 2025:

	Three Months Ended September 30,			
	2026	2025	$ Change	% Change
	(in thousands)			
CROs and other clinical development related third-party vendor expenses	$ 37,946	$ 21,143	$ 16,803	79%
Compensation and related benefits	13,029	9,624	3,405	35%
Stock-based compensation	7,693	2,582	5,111	198%
Other research and development expenses	8,930	6,602	2,328	35%
Total research and development expenses	$ 67,598	$ 39,951	$ 27,647	69%

Research and development expenses for the three months ended September 30, 2026 increased by $27.6 million, or 69%, compared to the same period in 2025. The increase primarily reflects (i) increased patient enrollment in our pivotal Phase 3 OPERA-01 and OPERA-02 clinical trials for palazestrant, continued advancement of our Phase 1b/2 OP-3136 clinical program, and increased manufacturing and clinical supply activities supporting these programs, and (ii) higher personnel-related costs, including increased non-cash stock-based compensation expense associated with equity awards granted at higher market prices and increased headcount.

General and administrative expenses

General and administrative expenses for the three months ended September 30, 2026 increased by $4.0 million, or 68%, compared to the same period in 2025. The increase primarily reflects the continued investment in personnel and corporate infrastructure to support our expanding late-stage clinical development activities and early preparations for the potential commercialization of palazestrant, including higher non-cash stock-based compensation of $2.7 million associated with equity awards granted at higher market prices, and increased professional fees of $1.0 million.

Other Income

Other income for the three months ended September 30, 2026 was primarily attributable to higher interest income, partially offset by a loss on sale of equipment and other loss due to unfavorable foreign currency exchange rate fluctuations.

Comparison of the nine months ended September 30, 2026 and 2025

The following table summarizes our results of operations for the nine months ended September 30, 2026 and 2025:

	Nine Months Ended September 30,			
	2026	2025	$ Change	% Change
	(in thousands)			
Operating expenses:				
Research and development	$ 174,615	$ 114,477	$ 60,138	53%
General and administrative	28,075	14,137	13,938	99%
Total operating expenses	202,690	128,614	74,076	58%
Loss from operations	(202,690)	(128,614)	(74,076)	58%
Other income:				
Interest income	13,337	12,214	1,123	9%
Other (loss) income	(535)	10	(545)	*NM
Total other income	12,802	12,224	578	5%
Net loss	$ (189,888)	$ (116,390)	$ (73,498)	63%

*NM - Not Meaningful

Research and development expenses

The following table summarizes our research and development expenses by functional area for the nine months ended September 30, 2026 and 2025:

	Nine Months Ended September 30,			
	2026	2025	$ Change	% Change
	(in thousands)			
CROs and other clinical development related third-party vendor expenses	$ 90,870	$ 48,376	$ 42,494	88%
Compensation and related benefits	36,777	27,432	9,345	34%
Stock-based compensation	23,155	9,592	13,563	141%
Other research and development expenses	23,813	19,077	4,736	25%
Milestone payment owed to Aurigene	—	10,000	(10,000)	(100)%
Total research and development expenses	$ 174,615	$ 114,477	$ 60,138	53%

Research and development expenses for the nine months ended September 30, 2026 increased by $60.1 million, or 53%, compared to the same period in 2025. The increase primarily reflects (i) increased patient

enrollment in our pivotal Phase 3 OPERA-01 and OPERA-02 clinical trials for and Phase 1/2 study of palazestrant, continued advancement of our Phase 1b/2 OP-3136 clinical program, and increased manufacturing and clinical supply activities supporting these programs, and (ii) higher personnel-related costs, including increased non-cash stock-based compensation expense associated with equity awards granted at higher market prices and increased headcount. These increases were partially offset by the absence of $10.0 million of milestone expense related to Aurigene in 2026 that was recognized in the same period in 2025.

General and administrative expenses

General and administrative expenses for the nine months ended September 30, 2026 increased by $13.9 million, or 99%, compared to the same period in 2025. The increase primarily reflects the continued investment in personnel and corporate infrastructure to support our expanding late-stage clinical development activities, and early preparations for the potential commercialization of palazestrant, including (i) an $8.3 million increase in non-cash stock based compensation expense associated with equity awards granted at higher market prices, (ii) a $3.7 million increase in professional fees associated with the build-out of our corporate infrastructure to support our continued growth, and (iii) a $1.4 million increase in payroll-related costs due to increased headcount.

Other Income

Other income for the nine months ended September 30, 2026 was primarily attributable to higher interest income, partially offset by an increase in other loss due to unfavorable foreign currency exchange rate fluctuations.

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 $189.9 million and $116.4 million for the nine months ended September 30, 2026 and 2025, respectively. From our inception through September 30, 2026, we had received aggregate net proceeds of $1.1 billion from sales of our common stock, convertible preferred stock and issuance of convertible promissory notes, stock option exercises, sale of stock through the Company's 2020 Employee Stock Purchase Plan (ESPP), and borrowings under our Credit Facility, as defined below.

As of September 30, 2026, we had $413.8 million in cash, cash equivalents and marketable securities and accumulated deficit of $787.4 million.

On September 5, 2023, we entered into a loan and security agreement (the Original Loan Agreement) with Silicon Valley Bank, a division of First Citizens Bank & Trust Company (the Bank), which provided us with an aggregate principal amount of up to $50.0 million (the Original Credit Facility), of which $25.0 million became available in September 2023 (Term Loan A) upon the closing of a private placement and the issuance of our common stock to selected institutional and accredited investors pursuant to a securities purchase agreement, and the remaining $25.0 million could have been made available upon approval of the Bank in its discretion. The Original Credit Facility was scheduled to mature on August 1, 2027. On June 28, 2024, we entered into the First Amendment to Loan and Security Agreement (the First Amendment) with the Bank, which, among other things, (i) increased 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 the Term Loan A of $25.0 million was immediately available, an additional $25.0 million became available upon achieving certain milestones related to the execution of a first-line pivotal Phase 3 clinical trial of palazestrant in combination with ribociclib (Term Loan B), and an additional $50.0 million which may be made available upon the approval of the Bank in its discretion (Term Loan C), and (ii) extended the maturity date to July 1, 2028. On June 27, 2025, we entered into a Second Amendment to Loan and Security Agreement (the Second Amendment) with the Bank, which, among other things, (i) decreased the interest rate to a floating rate equal to the greater of 6.0% or the prime rate, and (ii) extended the draw period of Term Loan A to January 15, 2026. As of September 30, 2026, we had an outstanding liability of $3.0 million under the Credit Facility, representing the full amount drawn to date. On

January 11, 2026, we entered into the Third Amendment to Loan and Security Agreement (the Third Amendment), which, among other things, (i) extended the draw period of Term Loan A to January 31, 2027, (ii) extended the draw period of Term Loan B to January 31, 2027, (iii) extended the draw period of Term Loan C to January 31, 2027, and (iv) extended the Maturity Date to January 1, 2029 (Maturity Date). Based on the occurrence of specified (a) development milestones related to the pivotal Phase 3 OPERA-01 clinical trial of palazestrant or (b) receipt of proceeds from capital financing, the draw period of Term Loan B and Term Loan C may be further extended to July 31, 2027, and the Maturity Date may be further extended to July 1, 2029. On July 1, 2026, the Company entered into the Fourth Amendment to Loan and Security Agreement (the Fourth Amendment, together with the Original Loan Agreement, as amended by the First Amendment, the Second Amendment, and the Third Amendment, the Loan Agreement), which, among other things, added Olema Oncology International Limited as a secured guarantor under the Loan Agreement.

On November 29, 2024, we entered into a securities purchase agreement for a private placement of (i) 19,928,875 shares of our common stock at a price of $9.08 per share and (ii) pre-funded warrants to purchase up to an aggregate of 7,604,163 shares of our common stock at a price of $9.0799 per pre-funded warrant, which represents the per share purchase price of the common stock sold in the private placement less the $0.0001 per share exercise price for each pre-funded warrant to selected institutional and accredited investors (the 2024 Private Placement). The aggregate gross proceeds for the 2024 Private Placement were approximately $250.0 million. After deducting offering expenses related to the 2024 Private Placement of approximately $13.0 million, the net proceeds to us from the 2024 Private Placement were approximately $237.0 million. Of the $13.0 million issuance costs, $6.5 million was paid in the fourth quarter of 2024 and $6.5 million was paid in the first quarter of 2025. Concurrently, on November 29, 2024, we entered in an exchange agreement with an investor and issued to such investor pre-funded warrants to purchase up to 3,420,000 shares of our common stock at an exercise price of $0.0001 per share, in exchange for 3,420,000 shares of our common stock previously outstanding and held by such investor. Thereafter, on January 10, 2025, we entered into exchange agreements with certain investors pursuant to which we issued pre-funded warrants to purchase up to 6,070,000 shares of our common stock at an exercise price of $0.0001 per share, in exchange for 6,070,000 shares of our common stock previously outstanding and held by such investors (Exchange Transactions). Certain holders of pre-funded warrants (together with such holder’s affiliates and other attribution parties) may not exercise pre-funded warrants held by them to the extent that immediately prior to or after giving effect to such exercise such holder would own more than 9.99% of our outstanding common stock immediately after exercise, which percentage may be changed at the holder’s election to a lower or higher percentage not in excess of 19.99% upon 61 days’ notice to us, subject to the terms of the pre-funded warrants. Refer to Note 12 of our notes to the condensed consolidated financial statements contained in this Quarterly Report for further information regarding the Exchange Transactions.

On January 6, 2025, we entered into a sales agreement (the Original 2025 Sales Agreement) with TD Securities (USA) LLC (TD Cowen), as sales agent, pursuant to which the Company may offer and sell, from time to time, shares of the Company's common stock, having an aggregate offering price of up to $150.0 million (the Original 2025 ATM Shares). The sales of the Original 2025 ATM Shares could be made by any method permitted that is deemed to be an 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 agreed to pay TD Cowen a commission of up to 3.0% of the aggregate gross proceeds from any 2025 ATM Shares sold by TD Cowen. On December 11, 2025, we entered into amendment no. 1 to the sales agreement (together with the Original 2025 Sales Agreement, the 2025 Sales Agreement), which increased the maximum aggregate offering price under the ATM program to $200.0 million (the 2025 ATM Shares). During the nine months ended September 30, 2026, we issued 1,712,739 shares of our common stock under the 2025 Sales Agreement at a weighted-average price of $24.92 for net proceeds of $41.9 million after deducting related issuance costs.

On November 19, 2025, we completed a follow-on public offering pursuant to which we sold 11,500,000 shares of common stock at a public offering price of $19.00 per share, including 1,500,000 shares sold pursuant to the underwriters’ full exercise of their option to purchase additional shares, resulting in aggregate net proceeds of $204.8 million, after deducting underwriting discounts and commissions and estimated offering costs. Sales of our common stock were made under our shelf registration on Form S-3, which we initially filed with the SEC on January 6, 2025 and that was declared effective by the SEC on January 15, 2025.

We expect to incur significant expenses and operating losses for the foreseeable future as we advance the clinical development of palazestrant, OP-3136, and nonclinical studies. We expect that our research and development and general and administrative costs will increase in connection with conducting additional nonclinical studies and clinical trials for our current and future research programs and product candidates, contracting with CMOs to support nonclinical studies and clinical trials, expanding our intellectual property portfolio, developing our commercialization capabilities, 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 nonclinical 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 September 30, 2026, as well as the available balance under the Credit Facility, will enable us to fund our current operating plan through mid-2028. We have based this estimate of cash runway on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

Refer to Notes 9, 10 and 11 of our notes to the condensed consolidated financial statements contained in this Quarterly Report 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 nine months ended September 30, 2026 to our commitments and contingencies disclosed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report.

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, nonclinical 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 scaling manufacturing capabilities to support late-stage development, regulatory submissions, and potential commercialization; 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 nonclinical 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. For example, our Loan Agreement includes covenants limiting our ability to, among other things, fund future acquisitions, make dividend payments, or obtain additional financing.

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:

	Nine Months Ended September 30,	
(in thousands)	**2026**	**2025**
Net cash used in operating activities	$ (138,995)	$ (108,389)
Net cash provided by investing activities	90,971	6,424
Net cash provided by (used in) financing activities	47,245	(2,255)
Net change in cash and cash equivalents	$ (779)	$ (104,220)

Operating activities

Net cash used in operating activities during the nine months ended September 30, 2026 consisted primarily of our net loss of $189.9 million, partially offset by $32.1 million of net non-cash adjustments and $18.7 million of changes in working capital. The net non-cash adjustments primarily consisted of $35.1 million of stock-based compensation expense, partially offset by $3.4 million of non-cash interest income on marketable securities.

The increase in other current liabilities of $25.8 million was mainly attributable to the timing of research and developmental expenditures, while the decrease in accounts payable of $8.0 million reflected the timing of vendor invoicing and related payments. The decrease in prepaid expenses and other current assets of $1.7 million primarily reflected the timing of payments, partially offset by an increase in other assets and long-term deposits of $0.7 million.

Net cash used in operating activities during the nine months ended September 30, 2025 consisted primarily of our net loss of $116.4 million, partially offset by $9.4 million of net non-cash adjustments and $1.4 million of changes in working capital. The net non-cash adjustments primarily consisted of $13.3 million of stock-based compensation expense, partially offset by $5.1 million of non-cash interest income on marketable securities. The net decrease in operating assets and liabilities was primarily due to (i) an increase of $5.6 million in other assets and long-term deposits due to project deposits paid to CROs as we advance OP-3136 and OPERA-02, (ii) a decrease of $1.2 million in accounts payable, which was primarily related to the timing of vendor invoicing and related payments, and (iii) an increase in prepaid expenses and other current assets of $1.0 million. These changes were partially offset by an increase of $7.4 million in other current liabilities that was mainly attributable to the timing of research and developmental expenditures.

Investing activities

Net cash provided by investing activities during the nine months ended September 30, 2026 was predominantly due to proceeds from maturities of marketable securities, partially offset by purchases of marketable securities and purchases of equipment.

Net cash provided by investing activities during the nine months ended September 30, 2025 was predominantly due to maturities of marketable securities which were partially offset by purchases of marketable securities.

Financing activities

Net cash provided by financing activities during the nine months ended September 30, 2026 consists primarily of $41.9 million of net proceeds from the issuance of shares under the at-the-market offering, $4.7 million of proceeds from the exercise of stock options, and $0.6 million of proceeds from the issuance of common stock under the employee stock purchase plan.

Net cash used in financing activities during the nine months ended September 30, 2025 was predominantly due to the $6.5 million payment of issuance costs related to the 2024 Private Placement, partially offset by $3.0 million draw down under our Credit Facility, $0.7 million from the sale of our common stock under the ESPP, and $0.5 million from the exercise of stock options.

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. 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 nine months ended September 30, 2026, there were no material changes to our critical accounting policies and estimates as reported in our Annual Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

During the nine months ended September 30, 2026, there were no material changes to our market risk disclosures reported in our Annual Report.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of September 30, 2026, management, with the participation of our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal 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 September 30, 2026, 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 fiscal quarter ended September 30, 2026 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, 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. 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 an NDA to the FDA or similar drug approval filings to comparable foreign authorities. If we are ultimately unable to obtain regulatory approval for palazestrant, OP-3136, or any future product candidates we may develop, 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 any future product candidates we may develop, 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 candidates we may develop.

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

- 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.

- If our information technology systems, our data, or those of the third parties with whom we work are or were compromised, we could experience adverse consequences resulting from such compromise, including, but not limited to, regulatory investigations or actions; litigation; fines; 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 nonclinical 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.

- For as long as we qualify as a “smaller reporting company” within the meaning of the Exchange Act, we 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, securing related intellectual property rights, conducting nonclinical studies and clinical trials, including conducting multiple Phase 1/2 studies of palazestrant, initiating and conducting Phase 3 clinical trials of palazestrant, conducting nonclinical studies of OP-3136, and conducting a Phase 1b/2 study 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 would 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 approved. 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 nonclinical 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 (EMA), or other regulatory authorities to perform clinical trials or nonclinical 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 any future product candidates we may develop, we expect to incur significant commercialization expenses related to drug sales, marketing, manufacturing and distribution. Our estimates as to how long until we are able to commercialize one or more of our product candidates are based on assumptions that may prove to be wrong, and we may require more time and resources than we currently anticipate, and may exhaust our available capital resources before we are able to generate any revenue from product sales. In addition, 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 and geopolitical uncertainty, market volatility, labor shortages, evolving trade and tariff policies, including related legal challenges, trade tensions, and retaliatory measures by other countries, supply chain disruptions, military conflicts, as well as any related political or economic responses or counter-responses by various global actors, inflationary pressures, monetary supply shifts, increased recession risk, 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, licensing arrangements, or other sources, which may dilute our stockholders, 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, increased in recent past 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 had previously raised, and may again raise in the future, 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. Higher interest rates may also limit our ability to access credit, equity, or other capital markets, or increase our cost of financing in those markets.

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 candidates we may develop 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, financial condition, results of operations, and prospects 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 our equity securities, including sales of our common stock and pre-funded warrants to purchase our common stock to selected institutional and accredited investors in private placement transactions, at-the-market offerings, our initial public offering and other public offerings and private financings. We have incurred net losses of $73.6 million and $42.2 million for the three months ended September 30, 2026 and 2025, respectively. We had an accumulated deficit of $787.4 million as of September 30, 2026. Our losses have resulted principally from expenses incurred in research and development of palazestrant and OP-3136, management and administrative costs, and other expenses that we have incurred while building our business infrastructure. Both our lead product candidate, palazestrant, and OP-3136 are 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 palazestrant or OP-3136 in one of our lead indications and proceed to commercializing palazestrant or OP-3136, 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 and nine months ended September 30, 2026 and 2025 included elsewhere in this Quarterly Report 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:

- completing clinical and nonclinical development of our product candidates and programs and identifying and developing new product candidates;

- seeking and obtaining marketing approvals for any product candidates that we develop;
- launching 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;
- achieving adequate access and reimbursement by government and third-party payors for product candidates that we develop;
- establishing 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;
- obtaining market acceptance of product candidates that we develop as viable treatment options;
- addressing any competing technological and market developments;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter and performing our obligations in such collaborations;
- maintaining, protecting, enforcing, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how;
- defending against third-party interference, infringement, or other intellectual property-related claims, if any; and
- attracting, hiring, and retaining qualified personnel.

Even if palazestrant, OP-3136, or any future product candidates that we may develop are 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 nonclinical 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.

On September 5, 2023, we entered into the Original Loan Agreement with the Bank, which provided us with the Original Credit Facility, of which $25.0 million became available in September 2023 as Term Loan A upon the closing of a private placement and the issuance of our common stock to selected institutional and accredited investors pursuant to a securities purchase agreement, and the remaining $25.0 million could have been made available upon approval of the Bank in its discretion. The Original Credit Facility was scheduled to mature on August 1, 2027. On June 28, 2024, we entered into the First Amendment with the Bank, which, among other things, (i) increased the aggregate principal amount of the Original Credit Facility from up to $50.0 million to up to $100.0 million of which the Term Loan A of $25.0 million was immediately available, an additional $25.0 million as Term Loan B became available upon achieving certain milestones related to the execution of a first-line pivotal Phase 3 clinical trial of palazestrant in combination with ribociclib, and an additional $50.0 million as Term Loan C which may be made available upon the approval of the Bank in its discretion, and (ii) extended the maturity date to July 1, 2028. On June 27, 2025, we entered into the Second Amendment with the Bank, which, among other things, (i) decreased the interest rate to a floating rate equal to the greater of 6.0% or the prime rate, and (ii) extended the draw period of Term Loan A to January 15, 2026. On January 11, 2026, we entered into the Third Amendment, which, among other things, (i) extended the draw period of Term Loan A to January 31, 2027, (ii) extended the draw period of Term Loan B to January 31, 2027, (iii) extended the draw period of Term Loan C to January 31, 2027, and (iv) extended the maturity date to January 1, 2029. Based on

the occurrence of specified (a) development milestones related to the pivotal Phase 3 OPERA-01 clinical trial of palazestrant or (b) receipt of proceeds from capital financing, the draw period of Term Loan B and Term Loan C may be further extended to July 31, 2027, and the maturity date (as so extended) may be further extended to July 1, 2029. On July 1, 2026, the Company entered into the Fourth Amendment, which, among other things, added Olema Oncology International Limited as a secured guarantor under the Loan Agreement. As of September 30, 2026, we had an outstanding liability of $3.0 million under the Credit Facility, representing the full amount drawn to date.

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; 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, 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; occurrence of any material adverse change; 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, thereby requiring us to repay the loan immediately. Any declaration by the Bank 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, nonclinical, 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 an NDA to the FDA or similar drug approval filings to comparable foreign authorities. If we are ultimately unable to obtain regulatory approval for palazestrant, OP-3136, or any future product candidates we may develop, 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 nonclinical 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. We have never submitted an NDA, and may receive a Refusal to File if there are deficiencies that preclude substantive review by FDA.

Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical 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 a 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 nonclinical 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 of our product candidates is found to be unsafe or lacking efficacy, we will not be able to obtain regulatory approval, 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 the composition of the patient populations, adherence to dosing regimens, and other trial protocols and the dropout rate among clinical trial participants. Patients treated with palazestrant, OP-3136, or any future product candidates we may develop 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 any future 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 trials of palazestrant or 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 we may develop to market, our ability to create long-term stockholder value will be limited.

In addition, we may rely in part on nonclinical, 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, nonclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in nonclinical 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 to support 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 that results in adverse consequences to us, including by 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 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 and 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 nonclinical studies or clinical trials;
- the data collected from clinical trials of palazestrant or OP-3136 may not be sufficient to support the submission of an 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, the European Commission, the competent authorities of the member states of the European Union (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, European Commission, or other comparable foreign regulatory authorities may significantly change in a manner that results in adverse consequences to us, including by rendering our clinical data insufficient for approval.

In connection with any future NDA submission for palazestrant, our third-party manufacturers and clinical trial sites will be subject to inspection for compliance with applicable laws and standards. If clinical data integrity is challenged or our manufacturers are found not to be in compliance, any NDA of ours under review may receive a Complete Response Letter rather than approval. Moreover, the FDA may convene an Advisory Committee in connection with review of a palazestrant NDA, and any adverse recommendations from such committee may result in a Complete Response Letter rather than 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 (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 success. 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 have had and may in the future experience delays in clinical trials of palazestrant, OP-3136, or any future product candidates we may develop. Our current or 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 (IRBs), or positive Ethics Committee opinions;
- 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 candidates 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 (cGMP) regulations or other applicable requirements, or infections or cross-contaminations of palazestrant, OP-3136, or any future product candidates 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 (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 currently do and may continue to do for palazestrant, OP-3136, or any future product candidates we may develop, 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 future product candidates we may develop, the commercial prospects of palazestrant, OP-3136, or any future product candidates we may develop will be harmed, and our ability to generate product revenues from palazestrant, OP-3136, or any future product candidates we may develop will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down palazestrant's, OP-3136's, or the development and approval process of any future product candidates we may develop 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 future product candidates we may develop. 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 future product candidates we may develop, our competitors may be able to bring products to market before we do, and the commercial viability of palazestrant, OP-3136, or any future product candidates we may develop 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 and OP-3136, 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 OP-3136, and we have expended, and plan to continue to expend, significant resources to pursue these and other indications for palazestrant and OP-3136. 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 candidates 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 candidates 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 candidates we may develop and jeopardize our ability to obtain marketing approval for the sale of palazestrant, OP-3136, or any future product candidates we may develop. 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 are developing palazestrant and OP-3136 and may develop future product candidates, in combination with other therapies, which exposes us to additional risks.

We are developing palazestrant and OP-3136 and may develop 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 study of palazestrant in a combination trial with a CDK4/6 inhibitor, an additional Phase 1/2 studies of palazestrant in combination with another CDK4/6 inhibitor and with a PI3Ka inhibitor, and a Phase 1b/2 study of palazestrant in combination with a CDK4 inhibitor. We have also initiated OPERA-02, a Phase 3 clinical trial of palazestrant in combination with a CDK4/6 inhibitor, ribociclib.

Even if palazestrant, OP-3136, or any future product candidates we may 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 candidates we may develop, are replaced as the standard of care for the indications we choose for palazestrant, OP-3136, or any future product candidates 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 any future product candidates we may develop 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 candidates 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, such as the potential for serious adverse effects, delays in their clinical trials and potential failure to receive approval from the FDA, European Commission or comparable foreign regulatory authorities.

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 pre-clinical and clinical development of our drug candidates.

We have previously in-licensed product candidates, and we may acquire or in-license potential product candidates in the future, as we continue to build our pipeline. Such arrangements with third parties 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 are 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 pre-clinical 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 candidates 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 nonclinical 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 candidates 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 have and may in the future publicly disclose preliminary or top-line data from our nonclinical 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 any future product candidates we may develop, 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 future product candidates we may develop.

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 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, marketed as ETCAMAH® by AstraZeneca PLC; imlunestrant, marketed as Inluriyo™ by Eli Lilly and Co.; vepdegestrant, marketed as VEPPANU™ by Rigel Pharmaceuticals, Inc.; and lasofoxifene, being developed by LeonaBio, Inc. There are also a number of KAT6 inhibitor product candidates in development that may compete with OP-3136 including prifetrastat and PF-08032562, being developed by Pfizer, MEN2312, being developed by Stemline Therapeutics, BG-75202 being developed by BeOne Medicines; IDE574, being developed by IDEAYA Biosciences, Inc.; and PRT13722, being developed by Prelude Therapeutics, Inc.

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 any future product candidates we may develop 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, and any future product candidates we may develop obsolete, less competitive, or not economical. If we are unable to compete

effectively, our opportunity to generate revenue from the sale of any product we may develop, if approved, would be adversely affected.

Changes in methods of palazestrant and OP-3136 manufacturing or formulation may result in additional costs or delay.

As palazestrant and OP-3136 progress through nonclinical 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 and OP-3136 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 or OP-3136 and jeopardize our ability to commercialize palazestrant or OP-3136, 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 for palazestrant, OP-3136, or any future product candidates we may develop, sales of such product will depend substantially, in the United States and internationally, on the extent to which the costs of the product are 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 (CMS), an agency within the U.S. Department of Health and Human Services (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. For example, HHS imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation. In addition, HHS has been empowered to negotiate the price of certain single-source drugs that have been on the market for at least seven (7) years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug

Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. 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, including European Union (EU) 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 candidates we may develop.

Palazestrant and OP-3136 are, and any future product candidates we develop 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 nonclinical 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 future product candidates 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 do, 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 or other actions, 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 an 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 are 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 any 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, which 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. For example, the most common side effects we have seen in patients treated with palazestrant in our clinical trials are nausea, fatigue, vomiting, constipation, headaches, and neutropenia. 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. 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 nonclinical 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 nonclinical 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. Critically ill patients enrolled in our clinical trials have experienced, and may in the future experience, deaths or other adverse medical events due to a variety of factors, including other therapies or medications that such patients may be using, the gravity of such patients' illnesses or other factors, and it may be difficult to determine the extent to which any particular adverse event or death is attributable to our product candidates, such other therapies or medications, or the patient's underlying illness.

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, including our potential collaboration, financing, or other business opportunities. Further, if palazestrant or OP-3136 obtains marketing approval, toxicities associated with palazestrant or OP-3136 that are not seen during clinical testing may develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional contraindications, addition of warnings, and precautions 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 nonclinical 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 are conducting 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, our international clinical trials are, and any additional international clinical trials will 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 nonclinical 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 EU, or applicable foreign regulatory authorities approve palazestrant, OP-3136, or any future product candidates we may develop, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, importation, exportation, and recordkeeping for palazestrant, OP-3136, or any future product candidates we may develop 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 ongoing 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 or other applicable 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 future product candidates we may develop and to generate revenue, 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 future product candidates we may develop. 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 candidates 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, government shutdowns 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, government budget and funding levels, ability to hire and retain key personnel, the acceptance and availability of user fee payments, and statutory, regulatory, and policy changes, and other events that may otherwise affect the FDA, EMA, the European Commission, 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 may continue to 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. Any reduction, delay, or interruption in such funding, whether due to recent or future budgetary constraints, could adversely affect our ability to operate our business, comply with applicable regulatory requirements, or access the capital markets.

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. For example, over the last several years, the U.S. government has shut down several times, including for 43 days beginning in October 2025, and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs again, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA 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 nonclinical 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 any 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, policies, 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 or other action that may arise from future legislative, judicial or executive 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 or face challenges in achieving or sustaining 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 and amendments to certain aspects of the ACA. For example, on July 4, 2025, the One Big Beautiful Bill Act (OBBBA) was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress has considered, and may continue to consider, legislation to extend or modify the expired ACA subsidies and other measures intended to reduce healthcare costs. 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 current administration will impact the ACA or our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. Such legislative changes also 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. Additionally, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective 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, on our business, financial condition, results of operations, and prospects.

The current administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS, and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced several agreements with major pharmaceutical companies that require the drug manufacturer to offer, through a direct-to-consumer platform (TrumpRx), U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions include, for example, directives to reduce agency workforce, program cuts, directing HHS to lower prescription drug costs for Medicare through a variety of initiatives, imposing tariffs on certain imported pharmaceutical products, and as part of the Make America Healthy Again, Commission's recent Strategy Report, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. The current administration is also pursuing other most-favored-nation drug pricing policies for certain prescription drugs. As part of these initiatives, the current administration is implementing or considering various CMS Center for Medicare and Medicaid Innovation models, under which manufacturers may owe rebates for certain prescription drugs under Medicaid or Medicare if the price of a drug included in an applicable model exceeds an international benchmark calculated based on prices available in certain reference countries. These include the finalized Global Benchmark for Efficient Drug Pricing Model (GLOBE) Model for certain Medicare Part B drugs; and the proposed Guarding United States Medicare Against Rising Drug Costs (GUARD) Model for certain Medicare Part D drugs, among others. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing operational costs and compliance risks.

In June 2024, in *Loper Bright Enterprises v. Raimondo*, the U.S. Supreme Court greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

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 June 15, 2026, the FDA approved Colorado's Section 804 Importation Program proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this and Florida's similar program, approved by the FDA in 2024, will be implemented and whether they will overcome potential legal, regulatory, or industry challenges in the United States and/or Canada. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs.

The likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad, is uncertain. As an example, the regulatory landscape related to clinical trials in the EU has evolved. The EU Clinical Trials Regulation (CTR), which was adopted in April 2014 and repeals the EU Clinical Trials Directive (CTD), became applicable on January 31, 2022. The CTR allows 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 by all EU Member States concerned, 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 via the centralized EU portal. Once the clinical trial is approved, clinical study development may proceed. The CTR foresaw a three-year transition period that ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our development plans.

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. The 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. On January 12, 2025, the HTA Regulation entered into application and has a phased implementation. The HTA Regulation is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and established a framework for joint clinical assessments, joint scientific consultations, and the early identification of emerging health technologies. The HTA Regulation permits EU Member States to use common HTA tools, methodologies, and procedures across the EU and requires them to rely on EU level joint clinical assessment reports for the clinical components of their national HTA evaluations. Individual EU Member States continue to be responsible for assessing nonclinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement.

In light of the fact that the United Kingdom has left the EU, the HTA Regulation will not apply in the United Kingdom. However, the 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. There can be no assurance that we will be able to obtain or sustain favorable pricing or reimbursement in the UK under these evolving frameworks, and any such inability could materially and adversely affect our anticipated revenues and growth prospects in that market.

Following a public consultation conducted in 2022, the United Kingdom enacted the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025, which came into force on April 28, 2026 following a 12-month implementation period. The amended regulations introduce a more streamlined and risk-proportionate framework for clinical trials, including combined regulatory and ethics review, new routes for lower-risk trials, and additional transparency requirements, while maintaining protections for trial participants and international good clinical practice standards. Although certain elements are consistent with the EU Clinical Trials Regulation, the United Kingdom and EU operate separate clinical trial regulatory systems. This divergence may

increase the cost and complexity of conducting multinational trials by requiring sponsors to satisfy separate UK and EU authorization, conduct, safety-reporting, transparency, manufacturing, and labeling requirements. Clinical trial data generated in the United Kingdom may nevertheless be used to support an EU marketing authorization application if the trials comply with applicable good clinical practice and ethical standards and generate reliable and robust data, and corresponding requirements apply when foreign clinical trial data are submitted to the MHRA.

Legislators, policymakers, and healthcare insurance funds in the EU and the United Kingdom 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 European 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.

On December 11, 2025, the European Parliament and the Council reached a provisional political agreement on the Pharma Package, which comprises a new directive and regulation intended to replace significant portions of the existing EU pharmaceutical framework. The reform encompasses a broad range of measures, including, among other things, changes to regulatory data and market protection periods, intellectual property exemptions intended to facilitate earlier generic and biosimilar market entry, marketing authorization procedures, and measures relating to the availability and supply of medicinal products. Under the agreed framework, medicinal products would generally benefit from eight years of regulatory data protection and one year of market protection, with opportunities to obtain additional market protection if specified conditions are satisfied. The Council formally adopted its first-reading position on September 28, 2026. The legislation remains subject to formal adoption by the European Parliament, following which it will be published in the Official Journal of the European Union. The new framework is expected to enter into force in late 2026 and to be subject to transitional arrangements, with general application not anticipated before 2028. Any reduction in regulatory protection available for our product candidates, together with measures facilitating earlier generic or, where applicable, biosimilar market entry, could increase competition and adversely affect the commercial prospects of any product candidates we are able to commercialize in the EU.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, our development, approval, or commercialization plans may be adversely affected.

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, if any, may be on the marketing approvals of palazestrant, OP-3136, or any future product candidates we may develop.

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 (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 (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 such 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 local laws require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state and/or the registration of pharmaceutical sales representatives in the jurisdiction. 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.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve ongoing 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 and the third parties with whom we work 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 (or third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; 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 GDPR imposes 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; and private litigation related to processing of personal data brought by classes of data subjects and consumer protection organizations authorized at law to represent their interests. Other jurisdictions in which we have in the past and may in the future conduct clinical trials or otherwise operate similarly have laws that apply to personal data and create potential liability for any non-compliance with such obligations.

In the ordinary course of business, we have in the past and may in the future transfer personal data from Europe and other jurisdictions to the United States and other countries. In the United States, the U.S. Department of Justice issued a rule entitled the Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restriction on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered persons that may impact certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified, or encrypted, which presents particular challenges for companies like ours and impacts our ability to enter into certain agreements and engage in certain data practices.

Europe and other jurisdictions have enacted data localization and data transfer laws. In particular, the 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 or have already adopted similarly stringent 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 and the UK Extension thereto (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 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. Also in Europe, NIS2 regulates resilience and incident response capabilities of entities operating in a number of sectors, including the health sector. Non-compliance with NIS2 may lead to significant financial penalties.

Numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 (CCPA)

applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses subject to the CCPA to provide specific disclosures in privacy notices and respond to requests of such individuals to exercise certain privacy rights. The CCPA creates the potential for financial liability and allows private litigants affected by certain data breaches to recover significant statutory damages. The CCPA and other comprehensive U.S. state privacy laws exempt some data processed in the context of clinical trials, but these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties with whom we work. These laws demonstrate our vulnerability to the evolving regulatory environment related to personal data 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, and may in the future become 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 and other adverse consequences.

Obligations related to data privacy and security (and individuals' 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, to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we work may not fully 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 data privacy or security laws, regulations, and other obligations could lead to significant consequences, including but not limited to fines, penalties (including criminal), regulatory investigations, lawsuits, significant costs for remediation, damage to our reputation, bans on processing personal data, orders to destroy or not use personal data, interruptions or stoppages in our business operations (including, as relevant, clinical trials), an 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 comply as well as to defend any claim or inquiry, adverse publicity, changes to our business model or operations, and 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 significant statutory damages, depending on the volume of data and the number of violations.

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 laws require changes in our data processing practices or if governing bodies interpret their laws in ways that negatively impact our business. Complying with our data privacy and security obligations has caused and may in the future cause us to incur costs and require changes to our business practices and compliance procedures.

We use artificial intelligence in certain aspects of our business, and challenges with properly managing its use could adversely affect our business.

Our employees and personnel as well as those of third parties with whom we work use artificial intelligence (AI), including generative AI, agentic AI and machine learning technologies to perform their work, and the disclosure and use of personal information and other information in such technologies is subject to various

privacy laws and other obligations. We incorporate AI technologies into certain aspects of our business, and applications of AI may become important in our operations over time. There are risks involved in developing and deploying AI, and there can be no assurance that the use of AI will enhance the development of our product candidates or be beneficial to our business, including our efficiency or profitability. Our competitors or other third parties may incorporate AI into their businesses more quickly or more successfully than us, which could impair our ability to compete effectively and adversely affect our results of operations. If we are unable to effectively use AI, it could make our business less efficient and result in competitive disadvantages.

Furthermore, governments have proposed, enacted, or are considering additional laws regulating AI, such as the EU AI Act and, in the U.S., the Colorado Artificial Intelligence Act, the California Bot Disclosure Law, the Utah Artificial Intelligence Policy Act, and the CCPA regulations on automated decision-making technology. For example, the EU AI Act sets out a risk-based framework, subjecting certain AI technologies to numerous compliance obligations, including transparency, conformity and risk assessment, and monitoring and human oversight requirements. Under the EU AI Act, non-compliant companies may be subject to administrative fines of up to 35 million Euros or 7% of a company's total worldwide annual turnover for the preceding financial year, whichever is higher. We expect other jurisdictions will adopt similar laws. It remains uncertain how these and other laws will apply to AI-generated content and related activities. Our use of AI technologies could result in additional compliance costs, regulatory investigations and actions, lawsuits, and other liabilities, ethical concerns, negative perceptions as to AI, or other complications that could adversely affect our business, reputation, or financial results.

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 (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. 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 products 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 products 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 products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm any potential international sales and adversely affect our future revenue, if any. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of any of products in international markets or, in some cases, prevent the export of our products 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 the future in decreased use of our products by, or in our decreased ability to export our products to potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell access to our products 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, results of operations, and prospects.

Our business 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 economic uncertainty, market volatility, labor shortages, evolving trade and tariff policies, including related legal challenges, trade tensions, and retaliatory measures by other countries, supply chain disruptions, military conflicts, as well as any related political or economic responses and counter-responses by various global actors, inflationary pressures, monetary supply shifts, increased recession risk, 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 uncertainty and developments, including the events noted above. General business and economic conditions that could affect our business, financial condition, results of operations, and prospects 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, have experienced periods of significant increases in the past few years, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity, and limitations 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.

International trade policies, including tariffs, sanctions, and trade barriers may adversely affect our business, financial condition, results of operations, and prospects.

We operate in a global economy which includes utilizing third-party suppliers in countries outside of the United States. The current international trade and regulatory environment is subject to significant ongoing uncertainty. There is inherent risk, based on the complex relationships among the United States and the countries in which we conduct our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The U.S. government has announced imposition of substantial tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, including with respect to the pharmaceutical industry. In response, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. These developments, including legal challenges related to such tariffs, have created a dynamic and unpredictable trade landscape, which may adversely impact our business, results of operations, financial condition, and prospects. The Bureau of Industry and Security, U.S. Department of Commerce, conducted an investigation under Section 232 of the Trade Act of 1962 to determine whether pharmaceutical ingredients, including finished drug product, manufactured outside the United States pose a national security risk and should be subject to additional tariffs. Based on this investigation, on April 2, 2026, the U.S. President issued a proclamation imposing up to a 100% tariff on certain patented pharmaceuticals and associated pharmaceutical ingredients. These tariffs became effective September 29, 2026 and will continue in effect unless they are expressly reduced, modified, or terminated. On

September 23, 2026, the U.S. Department of Commerce issued guidance to clarify the scope of these tariffs, including creating a process for seeking an exclusion for pharmaceutical products and associated ingredients that meet an urgent U.S. health need. We are continuing to monitor the potential impact of the proclamation, the guidance and any additional enabling regulatory actions on our business.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for clinical testing, as well as for manufacture of any products that we may commercialize, if approved. We also rely on specialized laboratory equipment, supplies, materials, and precursor compounds, all or part of which we believe may be ultimately sourced from multiple countries outside the United States, to advance our research and development efforts.

Notwithstanding legal challenges related to tariffs, we expect that current or future tariffs will result in increased research and development expenses, including with respect to increased costs associated with APIs, raw materials, laboratory equipment and research materials and components. In addition, such tariffs will increase our supply chain complexity and could also potentially disrupt our existing supply chain. Unlike consumer goods, pharmaceuticals face unique regulatory constraints that make rapid supply chain adjustments particularly difficult and costly. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence, which among other factors, could negatively impact our ability to secure additional financing on favorable terms or at all. In addition, as we advance toward commercialization in the future, if approved, tariffs and trade restrictions could hinder our ability to establish cost-effective production capabilities and impact negatively our growth prospects.

The complexity of announced or future tariffs, including as a result of uncertainty surrounding related legal challenges, may also increase the risk that we or our collaborators, partners, vendors, or suppliers may be subject to civil or criminal enforcement actions in the United States or foreign jurisdictions related to compliance with trade regulations. Foreign governments may also adopt non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities, which may limit our ability to compete internationally and attract non-U.S. investment, employees, customers and suppliers. Foreign governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions, or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the United States and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and may impose additional costs on or increase the complexity to our business.

Trade disputes, tariffs, restrictions, and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions, including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions, as well as of related legal challenges, remains uncertain and could materially and adversely affect our business, financial condition, results of operations, and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions, or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition, and prospects. In addition, tariffs and other trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this "Risk Factors" section.

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 future product candidates we may develop will be limited and the potential for successfully growing our business will be harmed.

We have never commercialized a product candidate before. If we are unable to establish sales, marketing, or distribution capabilities or enter into agreements with third parties to sell, market, or distribute palazestrant, OP-3136, or any future product candidates we may develop, we may not be able to successfully sell, market, or distribute palazestrant, OP-3136, or any future product candidate we may develop that obtain regulatory approval, if any.

We have never commercialized a product candidate and we currently do not have, and have never had, a sales force, or distribution or marketing capabilities. In order to commercialize any product candidates, if approved, we must build marketing, sales, supply, 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 candidates 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 future product candidates we may develop will be expensive and time-consuming, and will require significant attention of our executive officers to manage. Factors that may affect our ability to commercialize, if approved, palazestrant, OP-3136, or any future product candidates we may develop on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to and educating 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. Any failure or delay in the development of our internal sales, marketing, supply, and distribution capabilities could adversely impact the commercialization of palazestrant, OP-3136, or any future product candidates we may develop that we obtain approval to market, if any, 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 supply and 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 future product candidates we may develop 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, if any, either on our own or through collaborations with one or more third parties, we may not generate any revenue from such product candidate or be able to reach or sustain profitability, and we will incur significant additional losses.

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.

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 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 are 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 future product candidates we may develop 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 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 future product candidates we may develop and, accordingly, may not achieve our research, development and commercialization goals.

If our information technology systems, our data, or those of the third parties with whom we work are or were compromised, we could experience adverse consequences resulting from such compromise, including, but not limited to, regulatory investigations or actions; litigation; fines; 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, process) 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, personnel misconduct, and error, as well as 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, would 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 are increasingly 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, intentional misconduct, human and technological 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, natural disasters, 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, email, 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 have in the past and could in the future 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, access to or other compromise of our sensitive information or our information technology systems, or those of the third parties with whom we work. Despite the implementation of preventative and detective security measures, there can be no assurance that these measures will be effective.

We are not able to anticipate all types of security incidents, and we cannot implement preventive measures effective against all such security incidents. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to run our business. We could 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 we maintained certain practices, such as encryption and device security practices, to mitigate the risks associated with such events.

Additionally, the loss or other 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 data. We also rely on third parties to manufacture palazestrant, and similar events relating to their information 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.

It also may be difficult and/or costly to detect, investigate, mitigate, contain, and remediate any security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems. For example, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks. 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, OP-3136, and other therapeutics could be delayed, and we could be subject to significant fines, penalties, and other liabilities for any noncompliance with relevant privacy and security obligations such as laws, contracts, and privacy notices.

Applicable data privacy and security obligations require us to notify relevant stakeholders, including, as applicable, affected individuals, regulators, and others, 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 with whom we work) 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) and mass arbitrations; 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 relevant limitations of liability in relation to data privacy and security, 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 business disruption, security failure or security incidents. 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 products in the EU Member States.

We intend to seek approval to market palazestrant or OP-3136 in the United States and potentially in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for palazestrant or OP-3136, we will be subject to applicable rules and regulations in those jurisdictions. In some foreign countries, particularly those in the EU, the pricing of drugs is subject to governmental control and other market regulations, which could place pressure on the pricing and usage of palazestrant or OP-3136. In these countries, pricing negotiations with governmental authorities can take a considerable amount of time following 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 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 EU provides options for EU 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 (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, including in response to ongoing budgetary pressures on national healthcare systems, some of which were exacerbated by the COVID-19 pandemic. 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.

Portions of our net operating loss (NOL) carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or other restrictions. U.S. federal NOL carryforwards generated in tax years beginning 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 beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOL carryforwards in a year is limited to 80% taxable income in such year. In addition, at the state level, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited. For example, California 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 (the IRC), 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 of 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 international marketing of palazestrant, OP-3136, or any future product candidates we may develop, if approved, 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 geopolitical 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, maintain, and protect our proprietary rights and intellectual property in the United States and other countries for palazestrant, OP-3136 and any future product candidates that we may develop and technologies relating to their manufacture and uses. We generally seek to protect our proprietary position by, among other things, filing patent applications in the United States and abroad covering our product candidates such as palazestrant and OP-3136, proprietary technologies, and related manufacturing methods and uses that are important to our business, as well as inventions and improvements 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. In addition, we may seek to acquire or in-license relevant issued patents or pending patent applications from third parties. If we or our potential licensors are unable to obtain or maintain patent protection with respect to palazestrant, OP-3136, our proprietary technologies or 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 claimed technology unless and until patents issue, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications will result in the issuances of patents, that any issued patents will afford sufficient protection against competitors with similar technologies, or that such patents will not be infringed, designed around or invalidated by third parties.

Some of our patents and patent applications are co-owned with third parties, and any patents or patent applications that we may license in the future may be co-owned with third parties. If we are unable to obtain exclusive rights to a co-owner's interest in any such patent or patent application, the co-owner may, subject to applicable law and any governing agreement, be able to license its rights to other parties, including our competitors, which could market competing products or technologies. In addition, we may require the cooperation of such co-owners to enforce jointly owned patents against third parties, and such cooperation may not be provided to us.

Issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before patent offices or in courts. Accordingly, the extent of future protection of our proprietary rights is uncertain. Any protection we obtain may be limited and may not adequately protect our rights or enable us to obtain or maintain a 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 pending U.S. patent applications and corresponding foreign patent applications will be found patentable by the United States Patent and Trademark Office (USPTO) and by patent offices or courts in foreign countries. Nor can we be certain that the claims of 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 generally must be filed in advance of certain events (*e.g.,* third party filings, certain sales or offers for sale, or other activities that may constitute public disclosures) and we may be unaware of such events or may otherwise not succeed in filing applications before they occur;

- the USPTO and foreign patent authorities require compliance with numerous procedural, documentary, fee payment and other requirements during the patenting process, and noncompliance may result in abandonment or lapse of a patent or patent application or a partial or complete loss of patent rights;

- patent applications may not result in issued patent;
- patents may be challenged, invalidated, modified, revoked, circumvented, or found unenforceable, or may otherwise not provide a competitive advantage;
- the U.S. government and international governmental bodies may face significant pressure to limit the scope of patent protection in the United States and other countries; and
- patent laws in countries outside the United States may provide less effective protection than U.S. patent laws, potentially providing foreign competitors greater opportunities to create, develop and market competing products.

The patent prosecution process is also expensive, time-consuming and complex. We may be unable to file, prosecute, maintain, enforce or license all necessary or desirable patents and patent applications at a reasonable cost, in a timely manner, or in every jurisdiction where protection may be commercially advantageous. We may also fail to identify patentable aspects of our research and development activities before the occurrence of events that could preclude patent protection, such as public disclosure by us or a third party, public use, sale or offer for sale, or publication.

Although we enter into non-disclosure and confidentiality agreements with parties that have access to confidential or patentable aspects of our research and development activities, including employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors and other third parties, any such party may breach such agreements and disclose our information before a patent application is filed, thereby jeopardizing our ability to obtain patent protection. We also require our employees, commercial contractors, and certain consultants and investigators to enter into invention assignment agreements granting us ownership of discoveries or inventions made in the course of their employment or work on behalf of Olema. However, we cannot guarantee that we have entered into such agreements with every relevant party, all such agreements have been duly executed, or that a party will not breach an agreement and claim ownership of intellectual property that we believe is owned by us. Moreover, scientific publications often lag behind the underlying discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases, are never published. Accordingly, we cannot be certain that we were the first to invest, or the first to file patent applications covering inventions claimed in our owned, co-owned or licensed patents or patent applications.

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 and involve complex legal and factual questions, including questions for which important legal principles remain unresolved and have been the subject of substantial 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 issued patents that protect palazestrant or OP-3136 or effectively prevent others from commercializing competitive technologies and product candidates.

Moreover, the scope of claims in a patent application can be significantly narrowed before issuance, and the scope of an issued patent may be later reinterpreted. Legal standards governing the validity and enforceability of granted patent claims continue to evolve in the United States and elsewhere, and disputes over claim scope are common in the biopharmaceutical industry. Even if patent applications that we own or in-license issue as patents, such patents may not provide meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide a competitive advantage. Patents that we own or in-license may be

challenged, circumvented, narrowed, invalidated or found unenforceable. Consequently, we cannot be certain that palazestrant, OP-3136, or any future product candidates we may develop will be or will remain protected by valid and enforceable patents. Competitors or other third parties may design around our patents by developing similar or alternative technologies or products that do not infringe our claims, 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.

During examination, a patent office considers prior art relating to the claimed invention. Jurisdictions differ as to what information or events constitute "prior art" and when a patent application must be filed relative to potential prior art. Moreover, legal decisions may also change how particular information or events are treated to be considered as "prior art." In the United States, patent applicants must disclose to the USPTO information known to them that may be material to patentability. Patent examiners also conduct prior art searches; third parties may submit prior art for consideration during examination in the United States and in certain other jurisdictions.

We may be unaware of relevant prior art, may fail to identify or timely cite certain prior art, or may be unable to convince a patent examiner that our claims are patentable over the prior art. Because not all relevant prior art may be identified during examination, an issued patent may be susceptible to challenge based on art that was not considered by the patent office.

We may be subject to third-party pre-issuance submissions of prior art to the USPTO or other patent offices, and we may become involved in post-grant challenges such as opposition, derivation, revocation, reexamination, post-grant review (PGR), inter partes review (IPR), or other similar proceedings or litigation challenging our patent rights, including their validity or claims to priority. An adverse determination in any such submission, proceeding or litigation could narrow, invalidate or render unenforceable our patent rights and allow third parties to commercialize palazestrant, OP-3136, or any future product candidates we may develop and compete directly with us without payment. Such challenges, if successful, could limit our ability to stop others from using or commercializing similar or identical technologies and products, or limit the duration of 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 validity, for example, we cannot be certain that there is no invalidating prior art, including art of which we were unaware, and/or art which was not raised during prosecution. If a third party were to ultimately 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 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 may also result in substantial costs and consume significant management and scientific resources, even if the eventual outcome is favorable to us. In addition, any threat to the breadth or strength of our patent protection, regardless of outcome, 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 similar to palazestrant or any future product candidates we may develop that are not covered by the claims of the patents that we own or may in-license;

- 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, may not have been the first to make the inventions covered by the issued patents or patent applications that we own or may in-license in the future;
- we, or our current or future collaborators or license partners, may later be determined to not have been the first to file patent applications covering certain 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 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 of which we are unaware that could invalidate some or all claims of our patents;
- 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 develop additional proprietary technologies that are unpatentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to seek patent protection and preserve certain information as a trade secret, whereby a third party may subsequently obtain patent rights 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 one or more claims of a valid third party patent 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. The biopharmaceutical industry in general is subject to intellectual property challenges and litigation in the United States and abroad, including patent infringement lawsuits and proceedings before the USPTO and foreign patent offices, such as, e.g., oppositions, reexaminations, IPR proceedings and PGR proceedings. Companies in intellectual property-dependent

industries, including the biopharmaceutical industry, may employ intellectual property litigation as a means to gain a competitive advantage. Numerous third-party U.S. and foreign issued patents and pending patent applications with claims to compositions, formulations, methods of manufacture or treatment may exist in fields related to our product candidates, including palazestrant, OP-3136, or our future product candidates. 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.

One or more entities may hold patent rights to which we may wish to seek a license. If such entities decline to license those rights to us on reasonable terms, we may be unable to develop, manufacture, market, and commercialize products or services or perform research and development or other activities covered by these patents. If any such patents were to be asserted against us, we believe that we would have reasonable defenses, including non-infringement and invalidity. If our defenses are unsuccessful, we could be liable for significant damages, including treble damages and attorneys' fees if we are found to willfully infringe such patent(s). We may be required to obtain a license to such patent(s) that may not be available on commercially reasonable terms or at all. Without such a license, we could be precluded from commercializing a product candidate ultimately held to infringe such patent(s).

As the biopharmaceutical industry expands and more patents issue, the risk increases that palazestrant, OP-3136, or any future product candidates may become subject to third party patent infringement claims. Because patent applications remain confidential for a period of time after filing and may take years to issue, pending third party applications could later issue with claims that allegedly cover our product candidates or future product candidates, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Identifying third-party patent rights that may be relevant to our technology can be challenging; patent searches are imperfect, terminology varies amongst patents, databases may be incomplete and claim scope can be difficult to assess. Patents (or patent applications once granted) of which we are aware but believe to not be particularly relevant to our business may nonetheless be asserted against us, thereby potentially limiting our ability to make, use, sell, offer for sale or import future products or impair our competitive position. Third parties may obtain patents in the future and allege that our activities infringe such patents. The absence of infringement allegations to date provides no guarantee that such claims will not arise in the future. U.S. patent law provides a safe harbor for certain activities reasonably related to the development and submission of information to the FDA related to regulatory approval for therapeutic products under clinical development. The safe harbor provision no longer applies once activities shift away from being reasonably related to developing and submitting information reasonably related to regulatory approval.

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 an injunction against commercial activities relating to our products or processes could expose us to significant liability, including enhanced damages for willful infringement, and require us to obtain a license to manufacture or market palazestrant, OP-3136, or any future product candidates. Defending such claims, regardless of merit, would be costly and divert employee resources. We cannot predict whether we would prevail in any such actions or whether a required license would be made available on commercially acceptable terms, if at all. Even if we or a future strategic partner were to obtain a license, it might be nonexclusive, allowing competitors access to the same intellectual property. We may also be unable to redesign our product candidates or any future product candidates or processes to avoid infringement.

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, the extensive discovery required in intellectual property litigation or administrative proceedings creates a risk that some of our confidential information could be disclosed. Uncertainties arising from such proceedings could materially impair 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 what 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 technologies.

We may be unsuccessful in acquiring or in-licensing intellectual property rights to 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 competitive threat 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 a related 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 a patent infringement proceeding, a court may find that a patent we own or may in-license is invalid, unenforceable, and/or is not infringed, or may decline to

enjoin the challenged activity. If we or a future collaborator decide to enforce a patent with claims encompassing palazestrant, OP-3136, or a future product candidate, the defendant may counterclaim that the patent is invalid and/or unenforceable in whole or in part. Such counterclaims are common in U.S. patent litigation. Grounds for invalidity may include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, inadequate written description, lack of enablement, or obviousness-type double patenting. An unenforceability claim may allege, for example, that a person involved in prosecution withheld relevant information from the USPTO or made a material misrepresentation during prosecution.

The outcome following legal assertions of invalidity and/or unenforceability is unpredictable, and prior art could invalidate one or more claims of our patents. We cannot be certain that all potentially relevant prior art has been identified or that prior art we consider immaterial will not ultimately be found to affect the validity or enforceability of one or more of our patent claims.

If a defendant ultimately prevails on a legal assertion of invalidity and/or unenforceability, we may lose some or possibly all patent protection for a product candidate. In addition, a threat to the breadth or strength of our patent protection could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. A loss of patent protection could 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 expense, 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 adequately conduct such litigation or proceedings. 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 become compromised.

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 related to the commencement of litigation, results of hearings, rulings on motions, and other interim proceedings. 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 whether an invention was derived from another inventor 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 initiated by a third party or by us may be necessary to determine whether an inventor named in an earlier-filed application derived the claimed invention from an inventor named in a later filed application without authorization. An unfavorable outcome could require us to cease using the related technology or seek a license from the prevailing party.

Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Even in the event of a successful outcome, such proceedings 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.

Changes in patent laws or their interpretations 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.

Changes in patent laws or their interpretation in the United States or in other countries could increase the uncertainty and cost surrounding prosecution of patent applications and the enforcement or defense of issued patents. For example, the Leahy-Smith America Invents Act (the Leahy-Smith Act), enacted on September 16, 2011, significantly changed U.S. patent law and impacted patent prosecution as well as patent litigation. Among other changes, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first inventor to file" system. Subject to the requirements of patentability and applicable exceptions, the first inventor to file a patent application is generally entitled to a patent over another inventor who files later, even if the later-filing inventor conceived of the invention first. Accordingly, another party may obtain patent rights to an invention that we developed independently but for which it filed first. This requires us to be cognizant and carefully manage the time between invention and filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether our inventions are determined 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 in some cases, until issuance, we may be unable to determine whether we or our licensors are the first to file patent applications related to our product candidates or technologies.

The Leahy-Smith Act also includes a number of significant provisions that affect the way patent applications are prosecuted and may also impact patent litigation. These include third-party submissions 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 post-grant review, inter partes review, 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 the evidentiary standard for invalidating a patent claim in certain USPTO proceedings is lower than the evidentiary standard applied in U.S. federal court, a third party may succeed in invalidating one or more claims before the USPTO based upon evidence that might not be sufficient to prevail in a district court action. Accordingly, third parties may rely on USPTO procedures to challenge our patent claims that might survive a district court challenge. Changes to patent laws, such as the Leahy-Smith Act and its implementation, may therefore increase the uncertainty and cost of prosecuting our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents, 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.

Like other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry is technologically and legally complex, costly, time consuming and inherently uncertain. Changes in patent laws or their interpretation in the United States or other countries may diminish our ability to protect our inventions and obtain, maintain and enforce our intellectual property rights, adversely affect the value of our intellectual property, and increase the uncertainty and cost of prosecution 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. Congress or foreign legislative bodies may enact patent reforms that are unfavorable to us.

The U.S. Supreme Court has issued decisions narrowing the scope of patent protection available in certain circumstances or otherwise limiting patent owners' rights in certain situations. These developments have increased uncertainty regarding both our ability to obtain patents and the value of patents once obtained. Decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar foreign authorities could change the laws and regulations governing patents in unpredictable ways that weaken our ability to obtain new patents or enforce patents that we own or license or may 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.

We may fail to perfect ownership of patents, patent applications or other intellectual property. There is a risk that we may omit an inventor, incorrectly identify an inventor, or fail to establish an unbroken chain of title from inventors to us, potentially leading former employees or other third parties to challenge inventorship or ownership of our patents, patent applications or other intellectual property. Errors in inventorship or ownership may also impact priority claims. If we lose the benefit of priority for a patent filing, intervening prior art or other events may preclude issuance of a patent or invalidate an issued patent.

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 term and the protection a patent affords is limited. In the United States, a patent generally expires 20 years from the earliest effective non-provisional filing date, subject to any patent term adjustment or extension and provided that required maintenance fees are paid. Although certain adjustments or extensions may be available, there can be no assurance that any such adjustments or extensions will be obtained. Even with issued patents covering palazestrant, OP-3136, or any future product candidates we may develop, we may face competition after those patents expire. Given the amount of time required to develop, test and obtain regulatory approval of our product candidates, relevant patents protecting such candidates might expire before or shortly after commercialization. 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.

Maintenance fees, also referred to as annuities or renewal fees, must be paid at prescribed intervals to keep patents, and in some jurisdictions, patent applications, in force. Failure to timely pay these fees may cause a patent or application to prematurely lapse, and reinstatement may be unavailable. Limited resources may prevent us from maintaining patent protection for certain patents in every market. 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 circumstances of FDA approval of palazestrant, OP-3136, or any future product candidates we may develop, one or more of our U.S. patents or a licensor's patent may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Amendments). The Hatch-Waxman Amendments permit restoration of up to five years of patent term as compensation for patent term lost during clinical development and the FDA regulatory review process. No more than one patent may be extended for a particular FDA-approved product. The patent

term extension cannot extend the patent term beyond 14 years from the product approval date, and only claims covering the approved drug product, an approved method of use or a method of manufacturing the approved product receive the benefit of the extension. 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.

We may not be granted an extension if, for example, we fail to exercise due diligence during the testing or regulatory review period, miss an applicable deadline, apply after the relevant patent expires, or otherwise fail to satisfy statutory or regulatory requirements. The scope of patent protection or the duration of extension afforded could be narrower or less than requested. If we do not obtain an available patent term extension or restoration or obtain an extension that is less than requested, competitors may obtain approval for competing products sooner after our patents expire, potentially relying on and referencing our clinical and nonclinical data, and launch their products earlier than might otherwise be the case, which could significantly harm our business, financial condition, results of operations, and prospects.

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

Filing, prosecuting and defending Olema patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries may be less extensive or more difficult to enforce than those in the United States. Consequently, we may be unable to prevent third parties from practicing our inventions in ex-U.S. countries where we lack patent protection 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 may export those otherwise infringing products to territories where we have patent protection but enforcement is limited. Such products may compete with palazestrant, OP-3136, or future product candidates, and effective remedies may be unavailable.

Some countries do not provide the same degree of protection of intellectual property rights as the laws of the United States. Patent protection is generally pursued on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. We may elect not to seek patent protection in certain countries and therefore we will not have the benefit of patent protection in these countries. In addition, the legal systems of some countries, particularly developing countries, provide less effective protection or enforcement of patents and other intellectual property rights, particularly those relating to biopharmaceuticals. A number of companies have encountered significant challenges in protecting and defending their intellectual property rights in foreign jurisdictions. Thus, it could be difficult for us to stop the infringement, misappropriation or violation of our or our licensors' patents, or the marketing of competing products in violation of our proprietary rights in foreign countries with weak intellectual property protections. Proceedings to enforce our intellectual property and other proprietary rights in foreign jurisdictions could result in substantial costs, divert our efforts and attention from other aspects of our business, expose our and our licensors' patents to narrow interpretation and invalidity challenges, jeopardize our and our licensors' patent applications from issuance, and provoke third party claims. We may not prevail in a litigation, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our worldwide intellectual property enforcement efforts may not provide 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 a 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 patent applications become due at various points over the lifetime of our patents and patent applications. We have systems in place to remind us when such fees are due, and we rely on outside counsel and their patent annuity service to monitor the fee deadlines and make required payments. 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 filing and prosecution process. We rely on reputable law firms and other professionals to assist us with compliance, 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, in some circumstances, noncompliance can result in abandonment or lapse of a 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 and trade names to brand and market our company and our products. These marks or names may be challenged, infringed, circumvented or declared generic or found to infringe third party marks, and there is a risk that we may be unable to protect our rights to these trademarks and trade names, impairing our ability to build name recognition among potential partners or in markets of interest. Competitors may adopt similar trade names or trademarks, impeding our ability to build brand identity and possibly leading to market confusion. Owners of registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names may bring trade name or trademark infringement claims against us. If we are unable to establish and protect our name recognition based on our trademarks and trade names, we may be unable to compete effectively, and our business, financial condition, results of operations and prospects may be significantly harmed. 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.

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 assignment agreements with employees, consultants and advisors, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology or processes, that all such agreements have been duly executed, or that a party will not breach an agreement and disclose our proprietary information, including our trade secrets, or claim ownership of intellectual property that we believe is owned by us. Monitoring and detecting unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the protective measures we have taken to protect our intellectual property will be effective. We also may not obtain adequate remedies for a breach. Trade secret misappropriation claims are difficult, costly, and time-consuming to enforce, the outcome is unpredictable, and some courts in the United States and abroad may provide limited protection for trade secrets.

If a competitor or other third party lawfully obtains or independently develops information that we maintain as a trade secret, we generally cannot prevent that party from using the technology or information to compete with us. If this occurs or we otherwise lose trade secret protection, the value of the information may be materially reduced and our competitive position could be materially harmed. If we do not apply for patent protection prior

to a potentially disqualifying disclosure or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, our ability to obtain patent or trade secret protection 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 in the future enter into non-disclosure and confidentiality agreements to protect the proprietary information 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 previously worked for, or provided or may currently be providing consulting services to other biopharmaceutical companies, including our competitors or potential competitors. Although we seek to ensure that our employees, consultants, and advisors do not use others' proprietary information or know-how in their work for us, a third party may allege that we or our employees or consultants inadvertently or otherwise breached an agreement and/or wrongfully used or disclosed trade secrets or other proprietary information such that we may become subject to litigation. Defending such claims, regardless of merit, could involve substantial expense, and create a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such action, and intellectual property litigation, regardless of outcome, may generate negative publicity and could prohibit us from marketing or otherwise commercializing palazestrant, OP-3136, or any future product candidates or technologies we may develop. An adverse outcome could subject us to significant 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 a successful defense could result in substantial costs and present a distraction to our management team and other employees.

Parties making claims against us may be able to sustain the cost 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 in all relevant fields of use and in all territories in which we 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 competing products in territories within the scope of nonexclusive rights or outside the scope of 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 funding sources such that our licensors are not the sole and exclusive owners of the patents we in-license. 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, and any license we obtain may be non-exclusive, giving our competitors access to the same technologies licensed to us. We may then be required to expend significant time and resources to redesign our technology, product candidates, or manufacturing methods or to developing or licensing replacement technology, which may not be technically or commercially feasible. 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 technologies, 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 the 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, us, and our partners; and
- the priority of invention of patented technology.

Agreements under which we license intellectual property or technology are complex, and certain provisions in such agreements may be susceptible to differing interpretations. Resolution of any contract interpretation disagreement could narrow the scope of rights we believe that we hold to relevant intellectual property or technology, or increase our financial or other obligations under the relevant agreement, either of which could significantly harm our business, financial condition, results of operations, and prospects. If a dispute over licensed intellectual property prevents or impairs 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.

Despite our best efforts, a licensor may conclude that we have materially breached a license agreement and seek to terminate it, eliminating our ability to develop and commercialize products and technology covered by such license agreement. If an in-license is terminated, or the underlying patents fail to provide the intended exclusivity, competitors may be free 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 generated with 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 exercises its march-in rights, 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 nonclinical 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 nonclinical studies and clinical trials and to monitor and manage data for our ongoing nonclinical and clinical programs. We rely on these parties for execution of our

nonclinical 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, OP-3136, 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 and OP-3136 for nonclinical 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, OP-3136, or other drugs necessary for the development or commercialization of palazestrant or OP-3136, or may not be able to obtain 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 or OP-3136 for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of palazestrant and OP-3136 for nonclinical 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 and OP-3136 are sourced, in some cases, from a single-source

supplier. If we were to experience an unexpected loss of supply of palazestrant or OP-3136 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 and OP-3136, 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 or OP-3136 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 OP-3136 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 or OP-3136 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 OP-3136, 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 or OP-3136, 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, OP-3136, 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 or OP-3136 are unable to produce sufficient quantities for clinical trials or for commercialization of palazestrant or OP-3136, 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 3 clinical trial of palazestrant in combination with ribociclib in ER+/HER2- frontline advanced or metastatic breast cancer, we entered into a Clinical Trial Collaboration and Supply Agreement (the 2024 Novartis Agreement), pursuant to which Novartis is manufacturing and supplying ribociclib. If Novartis is unable to timely manufacture or supply ribociclib, or if the 2024 Novartis Agreement terminates and we are unable to obtain ribociclib on comparable terms, our Phase 3 clinical trial may be delayed and our costs to conduct this trial may increase significantly. Either of these outcomes would materially harm our business, financial condition, results of operations, and prospects.

Our current and anticipated future dependence upon others for the manufacture of palazestrant, OP-3136, or other drugs necessary for the development or commercialization of palazestrant or OP-3136 may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval, if any, 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 or OP-3136 for clinical trials or our products 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 nonclinical 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 contamination is discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remediate the contamination, which could delay our 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, if approved, 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 of palazestrant and OP-3136 and may enter into collaborations with third parties for the development or commercialization of palazestrant, OP-3136, or any future product candidates. If any such collaborations are not successful, we may not be able to capitalize on the market potential of palazestrant, OP-3136, or any future product candidates.

We have third-party collaborators for the development of palazestrant and OP-3136. Our likely collaborators for any future collaboration arrangements for palazestrant, OP-3136, or any future product candidates include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies, and biotechnology companies.

We have, and likely will have, limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of palazestrant, OP-3136, or any future product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving palazestrant, OP-3136, or any future product candidates 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 de-emphasize or elect not to pursue development and commercialization of palazestrant, OP-3136, or any future product candidates, or may choose 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, the availability of 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, OP-3136, or any future product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of palazestrant, OP-3136, or any future product candidates 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, OP-3136, or any future product candidates, 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 or at all, 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, 2024 to November 5, 2026 has ranged from a low of $3.06 to a high of $35.83. 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, these factors include:

- the timing and results of nonclinical 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
- the geopolitical and macroeconomic environment, generally, including geopolitical and economic uncertainty, market volatility, labor shortages, evolving trade and tariff policies, including related legal challenges, trade tensions, retaliatory measures by other countries, supply chain disruptions, military conflicts, as well as any related political or economic responses and counter-responses by various global actors, inflationary pressures, monetary supply shifts, increased recession risk, and related financial instability.

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

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 candidates 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 candidates 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 November 5, 2026, we had 87,606,263 shares of common stock and pre-funded warrants to purchase up to 13,594,149 shares of common stock outstanding (which are immediately exercisable at an exercise price of $0.0001 per share of common stock, subject to beneficial ownership limitations). Refer to Notes 2 and 12 of our notes to the condensed consolidated financial statements contained in this Quarterly Report for further information regarding the pre-funded warrants. Shares issued upon the exercise of any such pre-funded warrants as well as stock options 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 registration statements with the SEC to register all of the shares, including shares issuable upon the exercise of pre-funded warrants, issued in each of our private placement transactions for public resale, and are required to maintain effectiveness of both registration statements 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 such private placement have been sold pursuant to such registration statement, or (iii) such time as the shares issued in such 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. In December 2025, we filed an automatic shelf registration statement pursuant to which we may offer and sell shares from time to time, including the shares of common stock pursuant to our at-the-market offering program currently in place. 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 public or private equity offerings, debt financings, or other sources, including up-front payments and milestone payments from strategic collaborations. For example, in November 2025, we completed a public offering of 11,500,000 shares of our common stock, at a public offering price of $19.00 per share, including 1,500,000 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares. In addition, in January 2025, following the termination of a prior sales agreement, we entered into a new sales agreement with TD Cowen (as amended from time to time, the 2025 Sales Agreement), 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. On December 11, 2025, we entered into Amendment No. 1 to the 2025 Sales Agreement, which increased the maximum aggregate offering price under the at-the-market offering program to $200.0 million. 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 2025 Sales Agreement, your ownership interest will be diluted, our stock price could fall and the terms of such securities may include liquidation or other

preferences that adversely affect your rights as a stockholder. Future financing activities may result in dilution to stockholders, the 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, OP-3136, 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.

For as long as we qualify as a "smaller reporting company" within the meaning of the Exchange Act, we 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, 2025, we qualify as a "smaller reporting company" as defined in the Exchange Act. However, based on the market value of our voting and non-voting common stock held by non-affiliates as of the end of our second fiscal quarter for the year ending December 31, 2026, we expect that we will no longer qualify as a smaller reporting company. For as long as we remain a smaller reporting company, 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 (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. Once we no longer qualify as a smaller reporting company, we will be subject to increased disclosure and compliance obligations. The loss of smaller reporting company status and compliance with such additional obligations may increase our legal, accounting, and financial compliance costs and cause management and other personnel to divert attention from operational and other business matters to devote additional time to public company reporting requirements.

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. The OBBBA, the IRA, the Coronavirus Aid, Relief, and Economic Security Act and legislation commonly referred to as the Tax Cuts and Jobs Act made many significant changes to the U.S. tax laws. For example, the IRA 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.

Tax authorities may disagree with our positions and conclusions regarding certain tax positions, resulting in unanticipated costs, taxes, or non-realization of expected benefits.

A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, the U.S. Internal Revenue Service or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies, including amounts paid with respect to our intellectual property development. 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. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not

established a taxable nexus, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. A tax authority may take the position that material income tax liabilities, interest and penalties are payable by us, in which case, we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications may materially and adversely impact our operating activities, effective tax rate, deferred tax assets, operating income, and cash flows.

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 (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 certain activities more difficult, time-consuming, or costly, and increase demands on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly, and current reports regarding 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 also required to disclose, on a quarterly basis, any changes made to our internal control and procedures. 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 certain 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. Any such claims or litigation could result in substantial costs, and the time and resources needed to resolve them could divert our management's attention 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.

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.

Trading Plans or Rule 10b5-1 Trading Plans

During the quarter ended September 30, 2026, our directors and officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated the contracts, instructions or written plans for the purchase or sale of our securities set forth in the table below.

Name	***Position***	***Action***	***Date of Adoption/ Termination***	***Type of Trading Arrangement***		***Expiration Date***	***Total Shares of Common Stock to be Sold******
				Rule 10b5-1*	***Non-Rule 10b5-1***		
Shawnte Mitchell	***Chief Legal Officer***	***Adoption***	***September 30, 2026***	X		***December 29, 2027***	*Up to 60,000*

* Contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.

** "Non-Rule 10b5-1 trading arrangement" as defined in Item 408(c) of Regulation S-K under the Exchange Act.

*** Represents the maximum number of shares that may be sold pursuant to the **10b5-1 trading arrangement**. The number of shares to be sold was dependent on the satisfaction of certain conditions as set forth in the written plan.

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	Offer Letter by and between Olema Pharmaceuticals, Inc. and Jason O'Byrne, dated July 24, 2026.	8-K	001-39712	10.1	08/13/2026
10.2	Fourth Amendment to Loan and Security Agreement, dated July 1, 2026, between Silicon Valley Bank and Olema Pharmaceuticals, Inc.	10-Q	001-39712	10.3	08/10/2026
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 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: November 10, 2026

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

Date: November 10, 2026

By: /s/ Jason O'Byrne
Jason O'Byrne
Chief Financial Officer
(*Principal Financial Officer and Principal Accounting Officer*)

Exhibit 10.3

FOURTH AMENDMENT
TO
LOAN AND SECURITY AGREEMENT

This Fourth Amendment to Loan and Security Agreement (this "Amendment") is entered into this 1st day of July, 2026, 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 further amended by that certain First Amendment to Loan and Security Agreement dated as of June 28, 2024, as amended by that certain Second Amendment to Loan and Security Agreement dated as of June 27, 2025, and as further amended by that certain Third Amendment to Loan and Security Agreement dated as of January 11, 2026 (the "**Third Amendment**") (as the same may from time to time be further 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 (i) add Irish Subsidiary as a secured Guarantor to the Loan Agreement and (ii) amend the Loan Agreement to make certain revisions to the Loan Agreement as more fully set forth herein.

D. Bank has agreed to so (i) add Irish Subsidiary as a secured Guarantor to the Loan Agreement and (ii) 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 12.2 (Definitions). The following terms and their respective definitions set forth in Section 12.2 are hereby amended in their entirety and replaced with the following:

“ “**Guarantor**” is, jointly and severally, individually and collectively, (a) Irish Subsidiary, and (b) any other Person providing a Guaranty in favor of Bank.

“ “**Guaranty**” is, collectively, (a) the Irish Subsidiary Guaranty, and (b) any guarantee of all or any part of the Obligations, as the same may from time to time be amended, restated, modified or otherwise supplemented.”

“ “**Loan Documents**” are, collectively, this Agreement and any schedules, exhibits, certificates, notices, and any other documents related to this Agreement, the Perfection Certificate, the Irish Subsidiary Guaranty, the Irish Subsidiary Security Documents, 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.”

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

“ “**Fourth Amendment Effective Date**” is July 1, 2026.”

“ “**Irish Companies Act**” is the Irish law Companies Act 2014."

“ “**Irish Security Deed**” is the Irish law security deed dated July 1, 2026.”

“ “**Irish Shareholder Security Deed**” is the Irish law shareholder security deed Borrower has executed in favor of Bank charging its shares in Guarantor dated July 1, 2026.”

“ “**Irish Subsidiary Guaranty**” is that certain Unconditional Guaranty executed by Guarantor in favor of Bank dated July 1, 2026.”

“ “**Irish Subsidiary Security Documents**” are, collectively the Irish Security Deed and Irish Shareholder Security Deed.”

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. Ratification of Perfection Certificate. Borrower hereby ratifies, confirms and reaffirms, all and singular, the terms and disclosures contained in a certain Perfection Certificate dated as of June 28, 2024 between Borrower and Bank, as amended by Schedule 2 of the Third Amendment, and acknowledges, confirms and agrees that the disclosures and information provided to Bank in such Perfection Certificate have not changed in any material respect, as of the date hereof, except as set forth on Schedule 2 attached hereto.

6. Release by Borrower.

6.1 FOR GOOD AND VALUABLE CONSIDERATION, Borrower hereby forever relieves, releases, and discharges Bank and its present or former employees, officers, directors, agents, representatives, attorneys, and each of them, from any and all claims, debts, liabilities, demands, obligations, promises, acts, agreements, costs and expenses, actions and causes of action, of every type, kind, nature, description or character whatsoever, whether known or unknown, suspected or unsuspected, absolute or contingent, arising out of or in any manner whatsoever connected with or related to facts, circumstances, issues, controversies or claims existing or arising from the beginning of time through and including the date of execution of this Amendment (collectively "**Released Claims**"). Without limiting the foregoing, the Released Claims shall include any and all liabilities or claims arising out of or in any manner whatsoever connected with or related to the Loan Documents, the recitals hereto, any instruments, agreements or documents executed in connection with any of the foregoing or the origination, negotiation, administration, servicing and/or enforcement of any of the foregoing.

6.2 In furtherance of this release, Borrower expressly acknowledges and waives any and all rights under Section 1542 of the California Civil Code, which provides as follows:

> "**A general release** does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party." (Emphasis added.)

6.3 By entering into this release, Borrower recognizes that no facts or representations are ever absolutely certain and it may hereafter discover facts in addition to or different from those which it presently knows or believes to be true, but that it is the intention of Borrower hereby to fully, finally and forever settle and release all matters, disputes and differences, known or unknown, suspected or unsuspected; accordingly, if Borrower should subsequently discover that any fact that it relied upon in entering into this release was untrue, or that any understanding of the facts was incorrect, Borrower shall not be entitled to set aside this release by reason thereof, regardless of any claim of mistake of fact or law or any other circumstances whatsoever. Borrower acknowledges that it is not relying upon and has not relied upon any representation or statement made by Bank with respect to the facts underlying this release or with regard to any of such party's rights or asserted rights.

6.4 This release may be pleaded as a full and complete defense and/or as a cross-complaint or counterclaim against any action, suit, or other proceeding that may be instituted, prosecuted or attempted in breach of this release. Borrower acknowledges that the release contained herein constitutes a material inducement to Bank to enter into this Amendment, and that Bank would not have done so but for Bank's expectation that such release is valid and enforceable in all events.

6.5 Borrower hereby represents and warrants to Bank, and Bank is relying thereon, as follows:

(a) Except as expressly stated in this Amendment, neither Bank nor any agent, employee or representative of Bank has made any statement or representation to Borrower regarding any fact relied upon by Borrower in entering into this Amendment.

(b) Borrower has made such investigation of the facts pertaining to this Amendment and all of the matters appertaining thereto, as it deems necessary.

(c) The terms of this Amendment are contractual and not a mere recital.

(d) This Amendment has been carefully read by Borrower, the contents hereof are known and understood by Borrower, and this Amendment is signed freely, and without duress, by Borrower.

(e) Borrower represents and warrants that it is the sole and lawful owner of all right, title and interest in and to every claim and every other matter which it releases herein, and that it has not heretofore assigned or transferred, or purported to assign or transfer, to any person, firm or entity any claims or other matters herein released. Borrower shall indemnify Bank, defend and hold it harmless from and against all claims based upon or arising in connection with prior assignments or purported assignments or transfers of any claims or matters released herein.

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.

11.Effectiveness. This Amendment shall be deemed effective upon the due execution and delivery to Bank of (a) the Irish Subsidiary Guaranty, and (b) this Amendment by each party hereto.

[Signature page follows.]

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/ Tom Seminara	
Name: Tom Seminara	By: /s/ Sean Bohen
Title: Vice President	Name: Sean Bohen
	Title: President and Chief Executive Officer

Schedule 1

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 and Guarantor 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:
    o Yes, in compliance: _____

- o No, not in compliance: _____

E. If not in compliance with Line D: is Line A equal to Line B?
   - o Yes, in compliance: _____
   - o No, not in compliance: _____

F. If in compliance with Line D, is Line A greater than or equal to 65% (excluding the account balance maintained in the Permitted JPM Operating Account) of Line B
   - o Yes, in compliance: _____
   - o No, not in compliance: _____

G. Balance of accounts in the name of Australian Subsidiary: $_____
   - o Yes, in compliance: _____
   - o No, not in compliance: _____

H. Balance of accounts in the name of Irish Subsidiary during Irish Subsidiary Transition Period: $_____
   - o Yes, in compliance: _____
   - o 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:
   - o No, no Trigger Event or Cash Collateralization requirement: _____
   - o 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:

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					

Schedule 2

Perfection Certificate Updates

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, M.D., Ph.D., 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the 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(s) 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: November 10, 2026

By: /s/ Sean Bohen, M.D., Ph.D.
Sean Bohen, M.D., Ph.D.
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, Jason O'Byrne, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the 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(s) 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: November 10, 2026

By: /s/ Jason O'Byrne
Jason O'Byrne
Chief 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., President and Chief Executive Officer of Olema Pharmaceuticals, Inc. (the "Company"), and Jason O'Byrne, 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 September 30, 2026, 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: November 10, 2026

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

Date: November 10, 2026

By: /s/ Jason O'Byrne
Jason O'Byrne
Chief 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."