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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 June 30, 2022

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.)**
512 2nd Street, 4th Floor San Francisco, CA	**94107**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 243-5555

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of August 5, 2022, the registrant had 40,419,559 shares of common stock, $0.0001 par value per share, outstanding.

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PART I-FINANCIAL INFORMATION

Item 1. Financial Statements.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements.

Olema Pharmaceuticals, Inc.

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

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 24,526	$ 13,812
Marketable securities	216,185	273,438
Prepaid expenses and other current assets	2,315	3,435
Total current assets	243,026	290,685
Property and equipment, net	1,450	1,474
Operating lease right-of-use assets	3,028	3,246
Other assets	3,096	540
Total assets	$ 250,600	$ 295,945
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 120	$ 23
Operating lease liabilities, current	1,078	931
Other current liabilities	11,110	8,065
Total current liabilities	12,308	9,019
Operating lease liabilities, net of current portion	2,009	2,358
Total liabilities	14,317	11,377
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of June 30, 2022 and December 31, 2021; no shares issued and outstanding as of June 30, 2022 and December 31, 2021.	—	—
Common stock, $0.0001 par value; 490,000,000 shares authorized as of June 30, 2022 and December 31, 2021; 40,401,626 and 40,337,046 shares issued as of June 30, 2022 and December 31, 2021, respectively; 39,974,459 and 39,797,263 shares outstanding as of June 30, 2022 and December 31, 2021, respectively.	3	3
Additional paid-in capital	398,756	388,904
Accumulated other comprehensive loss	(2,398)	(149)
Accumulated deficit	(160,078)	(104,190)
Total stockholders' equity	236,283	284,568
Total liabilities and stockholders' equity	$ 250,600	$ 295,945

See accompanying notes to the condensed consolidated financial statements.

Olema Pharmaceuticals, Inc.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 27,054	$ 11,910	$ 43,063	$ 22,602
General and administrative	6,239	4,612	13,484	9,370
Total operating expenses	33,293	16,522	56,547	31,972
Loss from operations	(33,293)	(16,522)	(56,547)	(31,972)
Other income (expense):				
Interest income	415	117	633	228
Other income (expense):	20	(1)	26	(1)
Total other income	435	116	659	227
Net loss	$ (32,858)	$ (16,406)	$ (55,888)	$ (31,745)
Net loss per share, basic and diluted	$ (0.82)	$ (0.42)	$ (1.40)	$ (0.81)
Weighted average shares used to compute net loss per share, basic and diluted	39,918,219	39,415,330	39,876,650	39,370,809

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net loss	$ (32,858)	$ (16,406)	$ (55,888)	$ (31,745)
Other comprehensive loss:				
Net unrealized loss on marketable securities	(772)	(1)	(2,249)	(14)
Total comprehensive loss	$ (33,630)	$ (16,407)	$ (58,137)	$ (31,759)

See accompanying notes to the condensed consolidated financial statements.

Olema Pharmaceuticals, Inc.

Condensed Consolidated Statements of Stockholders' Equity (Unaudited)

(In thousands)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Equity
Balances at March 31, 2022	39,869,325	$ 3	$ 393,933	$ (1,626)	$ (127,220)	$ 265,090
Vesting of early exercised stock options	6,990	—	31	—	—	31
Vesting of restricted stock awards	49,319	—	—	—	—	—
Exercise of stock options	17,934	—	7	—	—	7
Issuance of shares under the employee stock purchase plan	30,891	—	57	—	—	57
Stock-based compensation expense	—	—	4,623	—	—	4,623
Employee stock purchase plan expense	—	—	105	—	—	105
Net unrealized loss on marketable securities	—	—	—	(772)	—	(772)
Net loss	—	—	—	—	(32,858)	(32,858)
Balances at June 30, 2022	39,974,459	$ 3	$ 398,756	$ (2,398)	$ (160,078)	$ 236,283

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Equity
Balances at December 31, 2021	39,797,263	$ 3	$ 388,904	$ (149)	$ (104,190)	$ 284,568
Vesting of early exercised stock options	13,979	—	62	—	—	62
Vesting of restricted stock awards	98,637	—	—	—	—	—
Exercise of stock options	33,689	—	40	—	—	40
Issuance of shares under the employee stock purchase plan	30,891	—	57	—	—	57
Stock-based compensation expense	—	—	9,497	—	—	9,497
Employee stock purchase plan expense	—	—	196	—	—	196
Net unrealized loss on marketable securities	—	—	—	(2,249)	—	(2,249)
Net loss	—	—	—	—	(55,888)	(55,888)
Balances at June 30, 2022	39,974,459	$ 3	$ 398,756	$ (2,398)	$ (160,078)	$ 236,283

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Equity
Balances at March 31, 2021	39,342,129	$ 3	$ 374,467	$ (13)	$ (48,433)	$ 326,024
Vesting of early exercised stock options	6,989	—	30	—	—	30
Vesting of restricted stock awards	116,571	—	—	—	—	—
Exercise of stock options	63,014	—	130	—	—	130
Issuance of shares under the employee stock purchase plan	23,885	—	386	—	—	386
Stock-based compensation expense	—	—	3,871	—	—	3,871
Employee stock purchase plan expense	—	—	50	—	—	50
Net unrealized loss on marketable securities	—	—	—	(1)	—	(1)
Net loss	—	—	—	—	(16,406)	(16,406)
Balances at June 30, 2021	39,552,588	$ 3	$ 378,934	$ (14)	$ (64,839)	$ 314,084

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Equity
Balances at December 31, 2020	39,308,238	$ 3	$ 371,228	$ —	$ (33,094)	$ 338,137
Vesting of early exercised stock options	13,979	—	61	—	—	61
Vesting of restricted stock awards	143,472	—	—	—	—	—
Exercise of stock options	63,014	—	130	—	—	130
Issuance of shares under the employee stock purchase plan	23,885	—	386	—	—	386
Stock-based compensation expense	—	—	7,015	—	—	7,015
Employee stock purchase plan expense	—	—	114	—	—	114
Net unrealized loss on marketable securities	—	—	—	(14)	—	(14)
Net loss	—	—	—	—	(31,745)	(31,745)
Balances at June 30, 2021	39,552,588	$ 3	$ 378,934	$ (14)	$ (64,839)	$ 314,084

See accompanying notes to the condensed consolidated financial statements.

Olema Pharmaceuticals, Inc.

Condensed Consolidated Statements of Cash Flows
(unaudited)
(In thousands)

	Six Months Ended June 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (55,888)	$ (31,745)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	169	40
Non-cash lease expense	648	—
Premium amortization and discount accretion on marketable securities, net	(26)	138
Stock-based compensation expense, including employee stock purchase plan expense	9,693	7,129
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	204	878
Other assets	(542)	—
Accounts payable	97	(322)
Other current liabilities	1,915	3,893
Operating lease liabilities	(632)	—
Net cash used in operating activities	(44,362)	(19,989)
Cash flows from investing activities:		
Purchase of equipment	(51)	(780)
Maturities of marketable securities	205,750	67,000
Purchases of marketable securities	(150,720)	(334,874)
Net cash provided by (used in) investing activities	54,979	(268,654)
Cash flows from financing activities:		
Proceeds from exercise of stock options	40	130
Proceeds from issuance of common stock under employee stock purchase plan	57	386
Net cash provided by financing activities	97	516
Net increase (decrease) in cash and cash equivalents	10,714	(288,127)
Cash and cash equivalents at beginning of period	13,812	338,549
Cash and cash equivalents at end of period	$ 24,526	$ 50,422
Supplemental disclosure of non-cash investing and financing activities:		
Reclassification of prepaid expenses and other current liabilities into other assets	$ 2,014	$ —
Purchases of property and equipment included in accounts payable or other current liabilities	$ 94	$ 63
Vesting of early exercised stock options	$ 62	$ 61

See accompanying notes to the condensed consolidated financial statements.

Olema Pharmaceuticals, Inc.
Notes to condensed consolidated financial statements

(Unaudited)

1. Nature of the Business and Basis of Presentation

Olema Pharmaceuticals, Inc. ("Olema" or the "Company") is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of next-generation targeted therapies for women's cancers. The Company is initially focused on developing therapies for the treatment of breast cancer. The Company's wholly owned, lead product candidate, OP-1250, is a novel oral therapy with combined activity as both a complete estrogen receptor ("ER") antagonist ("CERAN") and a selective ER degrader ("SERD"). It is currently being evaluated as a single agent in an ongoing Phase 1/2 clinical trial, and in Phase 1b combination with palbociclib, in patients with recurrent, locally advanced or metastatic estrogen receptor-positive ("ER+"), human epidermal growth factor receptor 2-negative ("HER2-") breast cancer.

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 has operations in Cambridge, Massachusetts. It operates in one business segment and therefore has only one reportable segment. The Company is subject to risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including, but not limited to, successful discovery and development of its product candidates, development by competitors of new technological innovations, dependence on key personnel, the ability to attract and retain qualified employees, protection of proprietary technology, compliance with governmental regulations, the impact of COVID-19, the ability to secure additional capital to fund operations and commercial success of its product candidates. OP-1250 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 $240.7 million of cash, cash equivalents and marketable securities at June 30, 2022, which management believes is sufficient to fund its operating expenses and capital expenditure requirements into the second half of 2024.

Impact of COVID-19

The extent of the impact of the COVID-19 pandemic on the Company's business, operations and development timelines and plans remains uncertain, and will depend on certain developments, including the duration of the outbreak and its impact on the Company's development activities, planned clinical trial enrollment, future trial sites, contract research organizations ("CROs"), third-party manufacturers, and other third parties with whom the Company does business, as well as its impact on regulatory authorities and the Company's key scientific and management personnel. During 2021 and 2022, although the Company modified its operations and practices due to the COVID-19 pandemic and to comply with federal, state and local requirements, its business, operations and development timelines were not material adversely affected. In October 2021, the Company re-opened its offices to administrative employees, however due to the resurgence of cases relating to the spread of the Delta and Omicron variants, the Company continued to limit access to its offices. In March 2022, the Company fully re-opened its offices to all employees and continues to comply with protocols implemented by respective health authorities. The Company continues to monitor developments related to COVID-19 and may close its offices again in the future as the COVID-19 pandemic continues to evolve. The extent to which the COVID-19 pandemic may affect the Company's business, operations and development timelines and plans in the future, including the resulting impact on its expenditures and capital needs, remains uncertain.

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 ("US 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 US GAAP for complete financial statements. These condensed consolidated financial statements include the accounts of Olema Pharmaceuticals, Inc. and its wholly-owned subsidiary, Olema Oncology Australia Pty Ltd incorporated on January 6, 2021. All intercompany balances and transactions have been eliminated upon consolidation.

Unaudited Interim Financial Information

The interim condensed consolidated balance sheet as of June 30, 2022, the statements of operations and comprehensive loss, and stockholders' equity for the three and six months ended June 30, 2022 and 2021, and the statements of cash flows for the six months ended June 30, 2022 and 2021 are unaudited. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual financial statements and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for the fair presentation of the Company's condensed consolidated financial statements included in this report. The financial data and the other information disclosed in these notes to the condensed consolidated financial statements related to the three- and six-month periods are also unaudited. The results of operations for the six months ended June 30, 2022 are not necessarily indicative of the results to be expected for the year ending December 31, 2022 or for any other future annual or interim period. The condensed consolidated balance sheet as of December 31, 2021 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 financial statements included in the Company's Form 10-K as filed with the SEC on February 28, 2022.

Use of Estimates

The accompanying condensed consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP"). The preparation of the condensed consolidated financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the condensed consolidated financial statements and reported amounts of expenses during the reporting period. Significant areas that require management's estimates include accruals of research and development expenses, including accrual of research contract costs, stock-based compensation assumptions, including the fair value of common stock. On an ongoing basis, the Company evaluates its estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that management believes to be reasonable under the circumstances. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents are defined as short-term, highly liquid investments with original maturities of 90 days or less at the date of purchase. Cash deposits are all in reputable financial institutions in the United States and as of June 30, 2022 and December 31, 2021. Cash and cash equivalents consisted of cash on deposit with U.S. banks, including the Company's bank account for its Australia subsidiary, denominated in U.S. dollars and Australian dollars and investments in interest bearing money market funds.

Marketable Securities

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

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

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

Concentration of Credit Risk and Other Risks and Uncertainties

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

The Company’s future results of operations involve a number of other risks and uncertainties. Factors that could affect the Company’s future operating results and cause actual results to vary materially from expectations include, but are not limited to, uncertainty of results of clinical trials and reaching milestones, uncertainty of regulatory approval of the Company’s current and potential future product candidates, uncertainty of market acceptance of the Company’s product candidates, competition from substitute products and larger companies, securing and protecting proprietary technology, strategic relationships and dependence on key individuals or sole-source suppliers.

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

Leases

In February 2016, the Financial Accounting Standards Board ("FASB") issued new lease accounting guidance in Accounting Standard Update ("ASU") 2016-02, *Leases*, and in July 2018 issued ASU 2018-10, *Codification Improvements to Topic 842, Leases*, and ASU 2018-11, *Leases (Topic 842): Targeted Improvements* (the foregoing ASUs collectively referred to as "Topic 842"). Under the new guidance, 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 consolidated statements of operations and comprehensive loss.

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

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

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

The Company elected to not apply the recognition requirements of Topic 842 to short-term leases with terms of 12 months or less. Additional information and disclosures required by Topic 842 are contained in Note 13 "Lease" in the Company's Form 10-K as filed with the SEC on February 28, 2022.

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 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 prepaid expenses and other current

assets. Such amounts are recognized as an expense as the goods are delivered or the related services are performed.

Costs incurred in obtaining technology licenses are charged immediately to research and development expense if the technology licensed has not reached technological feasibility and has no alternative future uses.

Reimbursements of certain costs associated with research activities performed under the agreement with Novartis Institutes for BioMedical Research, Inc. (“Novartis”) are recorded as a reduction of research and development expenses, as described in Note 10, Commitments and Contingencies – *Clinical Collaboration and Supply Agreement*.

Research Contract Costs and Accruals

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

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

Foreign Currency Transactions

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

Net Loss Per Common Share

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

Recent Accounting Pronouncements

The Company lost its status as an emerging growth company on December 31, 2021, when it qualified as a large accelerated filer based on its market capitalization as of June 30, 2021, according to Rule 12b-2 of the Securities Exchange Act of 1934, as amended. As a result, the Company adopted all accounting pronouncements formerly deferred under the extended transition period available for emerging growth companies according to public company standards at December 31, 2021.

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.

	June 30, 2022			
(in thousands)	Level 1	Level 2	Level 3	Total
Financial Assets				
Cash	$ 10,607	$ —	$ —	$ 10,607
Money market funds	13,935	—	—	13,935
Commercial paper	—	49,063	—	49,063
U.S. government treasury bills	121,791	—	—	121,791
Government-sponsored enterprise securities	—	45,331	—	45,331
Total	$ 146,333	$ 94,394	$ —	$ 240,727

(in thousands)	June 30, 2022 Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Financial Assets				
Cash and cash equivalents	$ 24,542	$ —	$ —	$ 24,542
Short-term marketable securities (<12 months to maturity)	179,140	9	(1,509)	177,640
Long-term marketable securities (>12 months to maturity)	39,443	—	(898)	38,545
Total	$ 243,125	$ 9	$ (2,407)	$ 240,727

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 does not believe that the unrealized losses are credit related but are rather a reflection of current market yields and/or current marketplace bid/ask spreads. The Company has not recognized an allowance for credit losses as of June 30, 2022. In addition, no marketable securities had been in a consecutive loss position for more than 12 months as of June 30, 2022.

As of June 30, 2022, all of the Company's cash and cash equivalents consisted of cash on deposit with U.S. banks denominated in U. S. dollars and Australian dollars.

4. Property and Equipment, net

Property and equipment, net consisted of the following (in thousands):

	June 30, 2022	December 31, 2021
Lab equipment	$ 1,784	$ 1,639
Computer equipment	59	59
Property and equipment, gross	1,843	1,698
Less: Accumulated depreciation	(393)	(224)
Property and equipment, net	$ 1,450	$ 1,474

5. Prepaid Expenses and Other Current Assets

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

	June 30, 2022	December 31, 2021
Prepaid insurance	$ 836	$ 1,766
Prepaid subscriptions and licenses	483	291
Prepaid research contracts	29	239
Prepaid clinical trial costs	—	916
Reimbursable research and development costs from a collaboration partner	516	—
Other	451	223
Total	$ 2,315	$ 3,435

6. Other Current Liabilities

Other current liabilities consisted of the following (in thousands):

	June 30, 2022	December 31, 2021
Accrued R&D related costs	$ 6,914	$ 2,645
Accrued employee bonuses	2,052	3,752
Accrued professional fees	1,529	1,011
Accrued payroll related costs	184	191
Early exercise of unvested stock options	144	206
Accrued taxes	70	88
Other	217	172
Total	$ 11,110	$ 8,065

7. Stock-Based Compensation

In 2014, the Company's Board of Directors and stockholders approved and adopted the 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 maximum aggregate number of shares that may be subject to awards and sold under the 2014 Plan as of December 31, 2019 was 717,360 shares, which was subsequently increased to 4,842,180 in September 2020. The 2014 Plan was terminated on the date the 2020 Equity Incentive Plan (the "2020 Plan"), which is described below, became effective, and no additional awards 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 Company's Board of Directors and stockholders approved and adopted the 2020 Plan. The maximum number of shares of common stock that may be issued under the 2020 Plan will not 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 Company's 2014 Plan that, on or after the 2020 Plan becomes effective, terminate or expire prior to exercise or settlement; are not issued because the award is settled in cash; are forfeited because of the failure to vest; or are 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 Company's board of directors no later than December 31 of the immediately preceding year. The maximum number of shares of the common stock that may be issued on the exercise of incentive stock options under the 2020 Plan is 19,483,530 shares. The 2020 Plan permits the grant of options restricted stock awards, stock appreciation rights, restricted stock unit awards, performance awards, and other awards.

In 2022, the Company's Board of Directors approved and adopted the 2022 Inducement Plan (the "2022 Inducement Plan"). Under the 2022 Inducement Plan, initially 2,000,000 shares of common stock were reserved for issuance.

The 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 Plan generally expire ten years after the date of grant.

Stock Option Valuation

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

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

	Six Months Ended June 30,	
	2022	2021
Risk-free interest rate	1.81%	0.62%
Expected term (in years)	6.02	5.98
Expected volatility	79.33%	77.08%
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, 2021	5,768,028	$ 15.99	8.82	$ 11,365
Granted	2,932,190	6.73	—	—
Exercised(1)	(47,668)	3.00	—	—
Forfeited	(227,497)	21.79	—	—
Outstanding as of June 30, 2022(2)	8,425,053	$ 12.69	8.75	$ 1,086
Options vested and exercisable as of June 30, 2022	2,551,362	$ 14.01	8.16	$ 637
Options expected to vest as of June 30, 2022	5,873,691	$ 12.11	9.00	$ 450

(1) Exercised amount includes vesting of early exercised options.

(2) Balance as of June 30, 2022 includes 32,619 unvested early exercised stock options.

Early Exercise of Stock Options

In September 2020, one employee and one non-employee paid $0.6 million to early exercise 135,525 options with exercise prices ranging from $4.406 per share to $4.824 per share. As of June 30, 2022, 102,906 of such shares had vested with the remaining shares vesting over their respective terms. The terms of the 2014 Plan permit certain option holders to exercise options before their options are vested, subject to certain limitations. The early exercised options are subject to the same vesting provisions in the original stock option awards. Shares issued as a result of early exercise that have not vested are subject to repurchase by the Company upon termination of the purchaser's employment, at the price paid by the purchaser. Such shares are not deemed to be outstanding for accounting purposes until they vest and are therefore excluded from shares outstanding and from basic and diluted net loss per share until the repurchase right lapses and the shares are no longer subject to the repurchase feature. A liability is recognized related to the cash proceeds of the unvested options and is reclassified into common stock and additional paid-in capital as the shares vest and the repurchase right lapses. Accordingly, the Company has recorded the unvested portion of the exercise proceeds of $0.1 million in other current liabilities as of June 30, 2022.

Restricted Stock Awards

In June 2020, the Company granted to certain employees 789,095 shares of restricted common stock (the "RSAs") under the 2014 Plan as consideration for services with a deemed value of $2.40 per share, or $1.9 million. The following table summarizes the restricted stock activity under the Plan during the six months ended June 30, 2022:

	Number of Shares	Grant Date Fair Value
Unvested restricted stock as of December 31, 2021	493,185	$ 2.40
Granted	—	—
Vested	(98,637)	2.40
Forfeited	—	—
Unvested restricted stock as of June 30, 2022	394,548	$ 2.40

2020 Employee Stock Purchase Plan

In 2020, the Company's board of directors and stockholders approved and adopted the 2020 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 Company's board of directors in the offering. The current offering period will consist of two (2) six month purchase periods (each a "Purchase Period") during which payroll deductions of the participants are accumulated under the ESPP. The last business day of each Purchase Period is referred to as the "Purchase Date." A total of 430,416 shares of common stock were initially reserved for issuance pursuant to the ESPP.

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 $0.2 million for the three and six months ended June 30, 2022, respectively.

Stock-Based Compensation Expense

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Research and development	$ 3,211	$ 2,288	$ 6,278	$ 4,022
General and administrative	1,517	1,633	3,415	3,107
Total	$ 4,728	$ 3,921	$ 9,693	$ 7,129

8. Net Loss Per Share

Net Loss Per Share

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Numerator:				
Net loss	$ (32,858)	$ (16,406)	$ (55,888)	$ (31,745)
Denominator:				
Weighted average shares used to compute net loss per share, basic and diluted	39,918,219	39,415,330	39,876,650	39,370,809
Net loss per share, basic and diluted	$ (0.82)	$ (0.42)	$ (1.40)	$ (0.81)

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:

	June 30,	
	2022	2021
Unvested restricted common stock	394,548	591,822
Options to purchase common stock	8,425,053	5,575,455
Employee stock purchase plan contingently issuable	70,477	5,919
	8,890,078	6,173,196

Included in the potentially dilutive options to purchase common stock noted above are 211,621 shares issued upon exercise of options under non-recourse notes receivable during 2015 (see Note 7, “Stock-Based Compensation” in the Company’s Form 10-K as filed with the SEC on February 28, 2022). The Company determined the purchase of the stock to be non-substantive, and as such, the shares subject to the promissory notes will not be deemed outstanding until such time as the promissory notes have been repaid. As of December 31, 2020, all outstanding principal and accrued interest relating to the Non-Recourse Notes were settled in full by the two noteholders, and as a result, the Company issued 211,621 shares of common stock to the noteholders and included these shares in the basic and diluted net loss per share for three and six months ended June 30, 2021. Also included in the potentially dilutive options to purchase common stock are 32,619 unvested stock options that were early exercised by an employee and a non-employee in September 2020 (see Note 7, “Stock-Based Compensation”). The Company determined the early exercises to be non-substantive as the shares were subject to repurchase rights. Accordingly, the Company has excluded these shares from the calculation of basic and diluted net loss per share for the three and six months ended June 30, 2022 and 2021.

9. Leases

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

On June 1, 2013, the Company entered into a management services agreement with MandalMed, Inc. ("MandalMed") (the "MandalMed Services Agreement") to have access to and use a portion of approximately 5,762 square feet of space for the use of laboratory benches, lab equipment, office space, and administrative and facilities services. The Company subsequently entered into six amendments to extend the lease term to November 2023. As part of the sixth amendment, the Company leased additional space of approximately 2,130 square feet (the "Additional Space") for a three year period commencing on December 1, 2020 and ending on November 30, 2023. According to the terms of the MandalMed Services Agreement, the Company paid a security deposit of less than $0.1 million and is required to pay monthly rent and common area charges.

On August 27, 2020, the Company entered into a lease agreement with 512 2nd Street LLC to lease approximately 3,500 square feet of office space in San Francisco, California (the "Office Space Lease Agreement"). The Office Space Lease Agreement is for a period of two years commencing on September 1, 2020 and ending August 31, 2022. In April 2022, the Company extended the Office Space Lease Agreement up to August 31, 2023 and has one year renewal option to extend the term up to August 31, 2024. According to the terms of the Office Space Lease Agreement, the Company paid a $0.1 million security deposit and is required to pay monthly rent and common area charges. The extension of the lease term was accounted for as a modification under Topic 842 and the Company recorded additional ROU asset and lease liability of $0.3 million and $0.3 million, respectively, in the condensed consolidated financial statements.

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

The following table summarizes total lease expense during the three and six months ended June 30, 2022 (in thousands):

	Three Months Ended June 30, 2022	Six Months Ended June 30, 2022
Straight-line operating lease expense	$ 325	$ 647
Short-term lease expense	60	120
Variable lease expense	10	20
Total operating lease expense	$ 395	$ 787

The following table summarizes supplemental cash flow information during the three and six months ended June 30, 2022 (in thousands):

	Three Months Ended June 30, 2022	Six Months Ended June 30, 2022
Cash paid for amounts included measurement of lease liabilities:		
Operating cash flows from operating leases	$ 317	$ 632
Supplemental noncash information on lease liability arising from obtaining a right-of-use asset	$ 297	$ 297

The following table summarizes the Company's future minimum lease payments and reconciliation of lease liabilities as of June 30, 2022 (in thousands):

Years Ending December 31,		
2022 (from July 2022)	$	641
2023		1,186
2024		799
2025		822
2026		69
Thereafter		—
Total future minimum lease payments		3,517
Less: Interest		(430)
Total lease liabilities at present value		3,087
Lease liabilities, current		1,078
Lease liabilities, non-current	$	2,009

The following table summarizes lease term and discount rate as of June 30, 2022:

	June 30, 2022
Weighted-average remaining lease term (years)	3.11
Weighted-average discount rate	8.71%

10. Commitments and Contingencies

Clinical Collaboration and Supply Agreement

On July 22, 2020, the Company entered into a non-exclusive clinical collaboration and supply agreement with Novartis Institutes for BioMedical Research, Inc. (“Novartis”) (the “Novartis Agreement”). The collaboration is focused on the evaluation of the safety, tolerability and efficacy of OP-1250 in combination with Novartis’ proprietary CDK4/6 inhibitor Kisqali® (ribociclib) and/or Novartis’ proprietary phosphatidylinositol 3-kinase inhibitor Piqray® (alpelisib) (collectively the “Novartis Study Drugs”) as part of the Company’s planned Phase 1b clinical trial of OP-1250 in patients with metastatic estrogen receptor-positive breast cancer. 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 OP-1250, and for packaging and labeling all drugs used in the clinical trials for the combined therapies (other than the Novartis Study Drugs). Novartis is responsible for manufacturing and delivering to the Company the Novartis Study Drugs in such quantities as reasonably needed for the clinical trials for the combined therapies. In accordance with an agreed budget, subject to certain thresholds, Novartis will reimburse the Company for a majority of the direct outside costs that the Company incurs related to conducting the activities under the agreed development plan in conducting the clinical trials for the combined therapies.

The Novartis Agreement will terminate upon completion of all activities outlined in the development plan and the relevant protocols. Either party may terminate the Novartis Agreement for the uncured material breach or insolvency of the other party, if it reasonably deems it necessary in order to protect the safety, health or welfare of subjects enrolled in the clinical trials for the combined therapies due to the existence of a material safety issue, or in certain circumstances for an unresolved clinical hold with respect to either the Novartis Study Drugs or OP-1250. In addition, Novartis may terminate the Novartis Agreement if certain disputes between the parties are not resolved after following the applicable dispute resolution procedures, and the Company may terminate

the Novartis Agreement in the event the Company terminates all clinical trials of the combined therapies other than due to a material safety issue or upon a clinical hold.

Costs associated with research activities performed under the agreement are included in research and development expenses in the accompanying condensed consolidated financial statements, with any reimbursable costs from Novartis reflected as a reduction of such expenses. For the three and six months ended June 30, 2022, costs reimbursable from Novartis were $0.5 million and $0.5 million, respectively. As of June 30, 2020, the receivable due from Novartis was $0.5 million, which is recorded under prepaid expenses and other current assets in the accompanying condensed consolidated financial statements.

Clinical Trial Agreement

In November 2020, the Company entered into a non-exclusive clinical trial agreement with Pfizer Inc. (“Pfizer”) (the “Pfizer Agreement”), to evaluate the safety and tolerability of OP-1250 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.

The Company is responsible for manufacturing, packaging and labeling OP-1250, and for packaging and labeling all drugs used in the clinical trials for the combined therapies (other than IBRANCE® (palbociclib)). Pfizer is responsible for manufacturing and delivering to us IBRANCE® (palbociclib) in such quantities as reasonably needed for the clinical trials for the combined therapies.

The Pfizer Agreement will terminate upon completion of all activities outlined in the study plan and the relevant protocols. Either party may terminate the Pfizer Agreement for the uncured material breach or insolvency of the other party, if it reasonably deems it necessary in order to protect the safety, health or welfare of subjects enrolled in the clinical trials for the combined therapies due to the existence of a material safety issue, or in certain circumstances for an unresolved clinical hold with respect to either the IBRANCE® (palbociclib) or OP-1250. In addition, either party may terminate the Pfizer Agreement if certain disputes between the parties are not resolved after following the applicable dispute resolution procedures or if either party determines to discontinue clinical development for medical, scientific, legal or other reasons.

The Pfizer Agreement does not grant any right of first negotiation to participate in future clinical trials, and each of the parties retains all rights and ability to evaluate their respective compounds. Costs incurred in connection to the Pfizer Agreement are included in the research and development expense in the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2022 and 2021.

License Agreement

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

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

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

The $8.0 million upfront payment was incurred in June 2022 and recorded as research and development expense in the condensed consolidated statements of operations and comprehensive loss. Costs incurred and milestones payments due to Aurigene prior to regulatory approval are recognized as research and development expenses in the period incurred. Payments due to Aurigene upon or subsequent to regulatory approval will be accrued as a provision to cost of sales in the period when achievement of respective milestone target is probable.

Management Services Agreements

The Company conducts research and development programs internally and through third parties that include, among others, arrangements with vendors, consultants, CMOs, and CROs. The Company has contractual arrangements in the normal course of business with these parties, however, the contracts with these parties are cancelable generally on reasonable notice within one year and the Company's obligations under these contracts are primarily based on services performed through termination dates plus certain cancelation charges, if any, as defined in each of the respective agreements. In addition, these agreements may, from time to time, be subjected to amendments as a result of any change orders executed by the parties. As of June 30, 2022, 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 of Directors and executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. As of June 30, 2022 and December 31, 2021, the Company had not incurred any material costs as a result of such indemnifications.

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

You should read the following discussion and analysis of our financial condition and results of operations together with the unaudited condensed consolidated financial statements and related notes that are included elsewhere in this Quarterly Report on Form 10-Q and the audited financial statements and related notes that are included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 filed with the U.S. Securities and Exchange Commission, or the SEC, on February 28, 2022, or our Annual Report on Form 10-K.

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

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of next generation targeted therapies for women's cancers. Our team has spent the past decade characterizing the structure and function of the estrogen receptor, or ER, a key driver of breast cancer in approximately 75% of patients, in order to develop more potent, oral therapies that completely inactivate this signaling pathway. Our lead product candidate, OP-1250, is a novel oral therapy with combined activity as both a complete ER antagonist, or CERAN, and a selective ER degrader, or SERD, which we believe will drive deeper, more durable responses than existing therapies. OP-1250, both as a monotherapy and in combination with inhibitors of cyclin-dependent kinase 4 and 6, or CDK4/6, demonstrated robust tumor shrinkage in several xenograft models, including a breast cancer brain metastasis model. In August 2020, we initiated an ongoing Phase 1/2 dose escalation and expansion trial evaluating OP-1250 for the treatment of recurrent, locally advanced or metastatic ER-positive, or ER+, human epidermal growth factor receptor 2-negative, or HER2-, breast cancer. We reported initial data from the Phase 1 dose escalation portion of this trial in November 2021, which provide proof-of-concept for OP-1250 as a monotherapy treatment for ER+/HER2- breast cancer. In June 2022, we selected 120 mg as the Recommended Phase 2 dose for OP-1250 to advance into Phase 2 evaluation. Phase 2 enrollment has initiated and will include three cohorts: patients with measurable disease (N=50), patients with non-measurable disease (N=15) and patients with CNS metastasis (N=15). In January 2022, we initiated a Phase 1b dose escalation trial evaluating OP-1250 in combination with palbociclib for the treatment of recurrent, locally advanced or metastatic ER-positive, or ER+, human epidermal growth factor receptor 2-negative, or HER2-, breast cancer. We expect to report updated monotherapy and initial combination data for OP-1250 in the fourth quarter of 2022. We own worldwide development and commercialization rights to OP-1250. We believe OP-1250's oral formulation and dual mechanism of action directly address the

limitations of current endocrine therapies, such as fulvestrant and tamoxifen, and position OP-1250 as a potential endocrine therapy of choice for the treatment of ER+ breast cancers. Our goal is to transform the standard of care for women living with cancers by developing more effective therapies that apply our deep understanding and collective expertise in endocrine-driven cancers, nuclear receptor activities and mechanisms of acquired resistance.

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.

As of June 30, 2022, we had cash, cash equivalents, and marketable securities of $240.7 million. Based on our current operating plan, we believe that our existing cash and cash equivalents will be sufficient to fund our planned operating expenses and capital expenditure requirements into the second half of 2024.

We have incurred significant operating losses since the commencement of our operations. Our net losses were $32.9 million and $16.4 million for the three months ended June 30, 2022 and 2021, respectively, and $55.9 million and $31.7 million for the six months ended June 30, 2022 and 2021, respectively. We expect to incur significant and increasing losses for the foreseeable future as we continue to advance our product candidate, and as we continue to operate as a public company. Our net losses may fluctuate significantly from period to period, depending on the timing of expenditures on our research and development activities. As of June 30, 2022, we had an accumulated deficit of $160.1 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 OP-1250 for the treatment of ER+ positive breast cancer;
- initiate nonclinical studies and clinical trials for any additional product candidates that we may pursue in the future;
- seek to discover and develop additional product candidates and further expand our clinical product pipeline;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;

- continue to scale up external manufacturing capacity with the aim of securing sufficient quantities to meet our capacity requirements for clinical trials and potential commercialization;
- establish a sales, marketing and distribution infrastructure to commercialize any approved product candidates and related additional commercial manufacturing costs;
- develop, maintain, expand, protect and enforce our intellectual property portfolio, including patents, trade secrets and know how;
- acquire or in-license other product candidates and technologies;
- attract, hire and retain additional clinical, scientific, quality control, and manufacturing management and administrative personnel;
- add clinical, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts;
- expand our operations in the United States and to other geographies; and
- incur additional legal, accounting, investor relations and other expenses associated with operating as a public company.

We also expect to increase the size of our administrative function to support the growth of our business. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials 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. Until such time that we can generate significant revenue from product sales or other sources, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, which could include income from collaborations, strategic partnerships or marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. We may be unable to raise additional funds or to enter into such agreements or arrangements on favorable terms, or at all. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic and otherwise. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations or financial condition, including requiring us to have to delay, reduce or eliminate our product development or future commercialization efforts. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our development efforts. We cannot provide assurance that we will ever be profitable or generate positive cash flow from operating activities.

The COVID-19 pandemic continues to evolve. As a result of the COVID-19 pandemic, we experienced some delays in setting up our current Phase 1/2 clinical trial and in clinical site initiation, including delays in recruiting clinical site investigators and clinical site staff, which we may experience again in the future for clinical trials. The extent of the impact of the COVID-19 pandemic on our business, operations and development timelines and plans, including the resulting impact on our expenditures and capital needs, remains uncertain, and will depend on certain developments, including the duration of the COVID-19 pandemic, frequency of outbreaks and its impact on our development activities, planned clinical trial enrollment, future trial sites, contract research organizations, or CROs, third-party manufacturers, and other third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. We continue to actively monitor the rapidly evolving situation related to the COVID-19 pandemic and may take further actions

that alter our operations, including those that may be required by federal, state or local authorities, or that we determine are in the best interests of our employees and other third parties with whom we do business. During 2021 and 2022, although we modified our operations and practices due to the COVID-19 pandemic and to comply with federal, state and local requirements, our business, operations and development timelines were not material adversely affected. In March 2022, we fully re-opened our offices to all employees and continue to comply with protocols implemented by respective health authorities. We continue to monitor developments related to COVID-19 and may close its offices again in the future as the COVID-19 pandemic continues to evolve. The extent to which the COVID-19 pandemic may affect our business, operations and development timelines and plans in the future, including the resulting impact on our expenditures and capital needs, remains uncertain.

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 product candidate OP-1250. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

External expenses include:

- expenses incurred in connection with the discovery and nonclinical development of our product candidates, including under agreements with third parties, such as consultants and CROs;
- costs of manufacturing products for use in our nonclinical studies and clinical trials, including payments to contract manufacturing organizations, or CMOs, and consultants;
- costs of funding research performed by third parties;
- costs of purchasing lab supplies and non-capital equipment used in designing, developing and manufacturing 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; and
- facility costs including rent, depreciation and maintenance expenses.

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

We expense research and development expenses in the periods in which they are incurred. Costs for certain activities, such as manufacturing and 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.

Research and development expenses to advance the development of our lead product candidate and nonclinical program were $27.1 million and $11.9 million for the three months ended June 30, 2022 and 2021, respectively, and $43.1 million and $22.6 million for the six months ended June 30, 2022 and 2021, respectively.

We expect our research and development expenses to increase substantially in absolute dollars for the foreseeable future as we advance OP-1250 or any other 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 OP-1250 or any other future product candidates we may develop may be affected by a variety of factors including but not limited to: the safety and efficacy of our product candidates, early clinical data, investment in our clinical program, the ability of collaborators to successfully develop our licensed product candidates, competition, manufacturing capability and commercial viability. We may never succeed in achieving regulatory approval for our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our OP-1250 or any other 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 OP-1250 or any other future product candidates we may develop may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. We are also unable to predict when, if ever, we will generate revenue from our product candidates to offset these expenses. Our expenditures on current and future nonclinical and clinical development programs are subject to numerous uncertainties in timing and cost to completion. The duration, costs and timing of nonclinical studies and 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 candidate, 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 a continued acceptable safety profiles of our products following approval; and
- obtaining and retaining key research and development personnel.

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

General and administrative

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

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

Total other income

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

Results of operations

Comparison of the three months ended June 30, 2022 and 2021

The following table summarizes our results of operations for the three months ended June 30, 2022 and 2021:

	Three Months Ended June 30, 2022	2021	$ Change
	(in thousands)		
Operating expenses:			
Research and development	$ 27,054	$ 11,910	$ 15,144
General and administrative	6,239	4,612	1,627
Total operating expenses	33,293	16,522	16,771
Loss from operations	(33,293)	(16,522)	(16,771)
Other income (expense):			
Interest income	415	117	298
Other income (expense)	20	(1)	21
Total other income	435	116	319
Net loss	$ (32,858)	$ (16,406)	$ (16,452)

Research and development expenses

Research and development expenses for the three months ended June 30, 2022 were $27.1 million, compared to $11.9 million for the three months ended June 30, 2021. The increase of $15.1 million was primarily due to increased spending in (i) advancing the clinical study for our lead product candidate OP-1250 and the associated contract manufacturing costs, (ii) other nonclinical research and discovery program costs, including the $8.0 million upfront payment in connection with the Aurigene Agreement, and (iii) personnel-related costs due to increased headcount, including non-cash stock-based compensation expenses increase of $0.9 million.

General and administrative expenses

General and administrative expenses for the three months ended June 30, 2022 were $6.2 million compared to $4.6 million for the three months ended June 30, 2021. The increase of $1.6 million was primarily due to increased spending in (i) personnel-related expenses, which was partially offset by a non-cash stock-based compensation expenses decrease of $0.1 million, and (ii) public entity related costs, including legal compliance and other corporate costs.

Other income

Other income for the three months ended June 30, 2022 was $0.4 million, which primarily consisted of interest income from our marketable securities.

Comparison of the six months ended June 30, 2022 and 2021

The following table summarizes our results of operations for the six months ended June 30, 2022 and 2021:

	Six Months Ended June 30, 2022	2021	$ Change
	(in thousands)		
Operating expenses:			
Research and development	$ 43,063	$ 22,602	$ 20,461
General and administrative	13,484	9,370	4,114
Total operating expenses	56,547	31,972	24,575
Loss from operations	(56,547)	(31,972)	(24,575)
Other income (expense):			
Interest income	633	228	405
Other income (expense)	26	(1)	27
Total other income	659	227	432
Net loss	$ (55,888)	$ (31,745)	$ (24,143)

Research and development expenses

Research and development expenses for the six months ended June 30, 2022 were $43.1 million, compared to $22.6 million for the six months ended June 30, 2022. The increase of $20.5 million was primarily due to increased spending in (i) advancing the clinical study for our lead product candidate OP-1250 and the associated contract manufacturing costs, (ii) other nonclinical research and discovery program costs, including the $8.0 million upfront payment in connection with the Aurigene Agreement, and (iii) personnel-related costs due to increased headcount, including non-cash stock-based compensation expenses increase of $2.3 million.

General and administrative expenses

General and administrative expenses for the six months ended June 30, 2022 were $13.5 million compared to $9.4 million for the six months ended June 30, 2022. The increase of $4.1 million was primarily due to increased spending in (i) personnel-related expenses, including non-cash stock-based compensation expenses increase of $0.3 million, and (ii) public entity related costs, including legal compliance and other corporate costs.

Other income

Other income for the six months ended June 30, 2022 was $0.7 million, which primarily consisted of interest income from our marketable securities.

Liquidity and capital resources

Sources of liquidity

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from our operations. Our net losses were $32.9 million and $16.4 million for the three months ended June 30, 2022 and 2021, respectively, and $55.9 million and $31.7 million for the six months ended June 30, 2022 and 2021, respectively. Through June 30, 2022, we had received aggregate gross proceeds of $392.8 million from sales of our common stock, convertible preferred stock and issuance of convertible promissory notes, stock option exercises, and the sale of stock through the ESPP.

As of June 30, 2022, we had $240.7 million in cash, cash equivalents and marketable securities. As of June 30, 2022, we had accumulated deficit of $160.1 million. We had no debt outstanding as of June 30, 2022.

We expect to incur significant expenses and operating losses for the foreseeable future as we advance the nonclinical and clinical development of OP-1250. 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, 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 OP-1250 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.

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 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 continue the research and development of, continue or initiate clinical trials of, and seek marketing approval for, our product candidates. 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 existing cash, cash equivalents, and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2024 at which point we would need to obtain substantial additional funding in connection with our continuing operations. 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 candidate;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we enter into;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under collaboration agreements, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of securing manufacturing arrangements for commercial production; and

- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our product candidates.

Identifying potential product candidates and conducting 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 candidate, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of a product candidate 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, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

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

Cash flows

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

(in thousands)	Six Months Ended June 30, 2022	2021
Net cash used in operating activities	$ (44,362)	$ (19,989)
Net cash provided by (used in) investing activities	54,979	(268,654)
Net cash provided by financing activities	97	516
Net increase (decrease) in cash and cash equivalents	$ 10,714	$ (288,127)

Operating activities

Net cash used in operating activities in the six months ended June 30, 2022 consisted primarily of our net loss of $55.9 million, partially offset by non-cash charges of $9.9 million and a net increase in operating assets and liabilities of $1.7 million. The net loss consisted primarily of $43.1 million in research and development expenses and $13.5 million in general and administrative expenses. The non-cash charges consisted primarily of stock-based compensation of $9.7 million and depreciation and amortization expenses of $0.1 million, and non-cash lease expense of less than $0.1 million, net of cash payments of $0.6 million. The net increase in operating assets and liabilities was primarily due to (i) an increase of $1.9 million in other current liabilities, (ii) an increase of $0.1 million in accounts payable, which is primarily a result of timing of invoice payment, and (iii) a decrease of $0.2 million in prepaid expenses and other current assets. The changes are partially offset by a net increase of $0.5 million in other assets.

Net cash used in operating activities in the six months ended June 30, 2021 consisted primarily of our net loss of $31.7 million, partially offset by non-cash charges of $7.3 million and a net change of $4.4 million in net operating assets and liabilities. The net loss consisted primarily of $22.6 million in research and development expenses and $9.4 million in general and administrative expenses. The non-cash charges consisted primarily

of stock-based compensation of $7.1 million and depreciation and amortization expenses of $0.2 million, primarily related to premium amortization on our marketable securities. The change in operating assets and liabilities was primarily due to an increase of $3.9 million in other current liabilities, primarily related to the increased spending in (i) research and development related costs, including contract manufacturing and CRO expenses as a result of our continued advancement of our lead product program, and (ii) personnel related expenses, including employee bonuses, due to increased headcount, and a decrease in prepaid expenses and other current assets of $0.9 million.

Investing Activities

Net cash provided by investing activities in the six-month ended June 30, 2022 was predominately due to maturities of marketable securities which was partially offset by purchase of marketable securities.

Net cash used in investing activities in the six months ended June 30, 2021 was predominately due to purchases of marketable securities which was financed through the proceeds from the IPO and convertible preferred stock sale, and purchases of equipment, partially offset by the maturities of marketable securities.

Financing activities

Net cash provided by financing activities during the six months ended June 30, 2022 represents $0.1 million in net proceeds from the sale of our common stock under the 2020 ESPP and exercise of stock options.

Net cash provided by financing activities in the six months ended June 30, 2021 consisted of $0.4 million and $0.1 million in net proceeds from the sale of our common stock under the 2020 ESPP and the exercise of stock options, respectively.

Critical accounting policies and significant judgements and estimates

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

During the six months ended June 30, 2022, there were no material changes to our critical accounting policies and estimates as reported in our Annual Report on Form 10-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

During the six months ended June 30, 2022, there were no material changes to our market risk disclosures reported in our Annual Report on Form 10-K.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of June 30, 2022, management, with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and

procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2022, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended June 30, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. We have not experienced any material impact to our internal controls over financial reporting despite the fact that most of our employees are working remotely due to the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 situation to minimize the impact to the design and operating effectiveness of our internal controls.

PART II-OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently a party to any material litigation or other material legal proceedings.

Item 1A. Risk Factors.

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

RISK FACTOR SUMMARY

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

- We have not completed any clinical trials and 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 will 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 only product or future commercialization efforts.
- We have incurred net losses since inception, and we expect to continue to incur net losses for the foreseeable future. We 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 OP-1250. 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 only product candidate, OP-1250, which is currently in the early stages of clinical development. We cannot assure you that our planned clinical development programs for OP-1250 will be completed in a timely manner, or at all, or that we will be able to obtain approval for OP-1250 from the FDA, or any comparable foreign regulatory authority. If we are unable to complete development of, obtain regulatory approval for and commercialize OP-1250 in one or more indications and in a timely manner, our business, financial condition, results of operations and prospects will be significantly harmed.
- Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development. We have never completed a pivotal clinical trial or submitted a New Drug Application, or NDA, to the FDA or similar drug approval filings to comparable foreign authorities. If we are ultimately unable to obtain regulatory approval for OP-1250, 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, OP-1250 may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success. The degree of market acceptance would depend on a number of factors. If OP-1250 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 and 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 OP-1250, or product candidates we may develop in the future, our commercial opportunities will be negatively impacted.
- We may be unable to obtain U.S. or foreign regulatory approvals and, as a result, may be unable to commercialize OP-1250 or any future product candidate we may develop.
- The COVID-19 pandemic could adversely impact our business, including our nonclinical studies and clinical trials.
- 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. 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 the growth of our organization, particularly as we take on additional responsibility associated with being a public company. 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 OP-1250 and any other future product candidates we may develop and, accordingly, may not achieve our research, development and commercialization goals.
- Our internal computer systems, or those of any of our CROs, manufacturers, other contractors, consultants, collaborators or potential future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data, or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. Thus, the degree of future protection for our proprietary rights is uncertain.
- 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 OP-1250 or future product candidates we may develop and our business, financial condition, results of operations and prospects could be significantly harmed.

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

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

We have not completed any clinical trials and 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 product candidate, OP-1250, securing related intellectual property rights and conducting nonclinical studies and initiating a Phase 1/2 clinical trial of OP-1250. We have not yet demonstrated our ability to successfully complete any clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for you to accurately predict our future success or viability than it could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by clinical-stage biopharmaceutical companies in rapidly evolving fields. We also may need to transition from a company with a research focus to a company capable of successfully executing drug development activities and supporting commercial operations. If we do not adequately address these risks and difficulties or successfully make such a transition, our business, financial condition, results of operations and prospects will be significantly harmed.

We require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs of our only product 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, OP-1250. We anticipate incurring significant costs associated with the development of OP-1250 and any future drug candidates we may develop. Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or the EMA, or other regulatory agencies 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 OP-1250, we expect to incur significant commercialization expenses related to drug sales, marketing, manufacturing and distribution. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop. We also incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations.

As of June 30, 2022, we had $240.7 million in cash, cash equivalents, and marketable securities. Based on our current operating plans, we believe that our existing cash and cash equivalents, will be sufficient to fund our operating expenses and capital expenditures requirements into the second half of 2024. Our estimate as to how long we expect our existing cash and cash equivalents, 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 default in one or several of the financial institutions in which we hold, or 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, the COVID-19 pandemic and the macro-economic environment generally. Advancing the development of OP-1250 and any future product candidates we may develop will require a significant amount of capital, and our existing cash and cash equivalents will not be sufficient to fund all of the activities that are necessary to complete the development of OP-1250.

We will be required to obtain additional funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or 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 the COVID-19 pandemic, could also adversely impact our ability to access capital as and when needed. 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 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 our initial public offering and private financings. We have incurred net losses of $55.9 million for the six months ended June 30, 2022. We had an accumulated deficit of $160.1 million as of June 30, 2022. Our losses have resulted principally from expenses incurred in research and development of OP-1250 and from management and administrative costs and other expenses that we have incurred while building our business infrastructure. Our only product candidate, OP-1250, is in early-stage clinical trials. As a result, we expect that it will be several years, if ever, before we have a commercialized product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing OP-1250 in one of our lead indications, we expect that we will continue to incur substantial research and development and other expenses as we continue the clinical development programs for OP-1250 in other indications.

We 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 OP-1250. 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 six months ended June 30, 2022 and 2021 included elsewhere in this 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 OP-1250. 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, OP-1250 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 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 OP-1250 or any future product candidate that we may develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA, the EMA or other comparable regulatory agencies 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.

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

We are substantially dependent on the success of our only product candidate, OP-1250, which is currently in the early stages of clinical development. If we are unable to complete development of, obtain regulatory approval for and commercialize OP-1250 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 OP-1250, our only 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 OP-1250 in our ongoing clinical trials in multiple indications. We are investing significant efforts and financial resources in the research and development of OP-1250. OP-1250 will require additional clinical development, evaluation of clinical, nonclinical and manufacturing activities, marketing approval from government regulators, and significant marketing efforts before we can generate any revenues from product sales. We are not permitted to market or promote OP-1250 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 OP-1250 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 OP-1250 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 OP-1250 will be completed in a timely manner, or at all, or that we will be able to obtain approval for OP-1250 from the FDA, European Commission (based on the positive opinion of the Committee for Medicinal Products for Human Use of the EMA and commonly referred to as EMA approval), or any comparable foreign regulatory authority. If we are unable to complete development of, obtain regulatory approval for and commercialize OP-1250 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 clinical trial or submitted a New Drug Application, or NDA, to the FDA or similar drug approval filings to comparable foreign authorities. If we are ultimately unable to obtain regulatory approval for OP-1250, 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 early clinical trials of OP-1250 and any future product candidates we may develop may not be predictive of the results of subsequent clinical trials. We have a limited operating history and to date have not demonstrated our ability to complete large scale clinical trials.

Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through 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 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 product candidate is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and our business, financial condition, results of operations and prospects may be significantly harmed. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols and the dropout rate among clinical trial participants. Patients treated with OP-1250 or product candidates we may develop in the future may also be undergoing surgical, radiation and chemotherapy treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to OP-1250 or product candidates we may develop. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market OP-1250 or any future product candidates we may develop.

We do not know whether our current clinical trial of OP-1250 or any future clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market OP-1250 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 OP-1250 or any future product candidates to market, our ability to create long-term shareholder 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 OP-1250. 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, EMA 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 OP-1250 or any future product candidates we may develop. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, 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 OP-1250 or any future product candidates we may develop. Even if regulatory approval is secured for OP-1250, the terms of such approval may limit the scope and use of OP-1250, which may also limit its commercial potential. Furthermore, the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval, which may lead to the FDA, EMA or comparable foreign regulatory authorities delaying, limiting or denying approval of OP-1250, including and any other indication we are seeking for approval under OP-1250.

The regulatory approval processes of the FDA, EMA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for OP-1250 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, EMA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions.

Applications for OP-1250 could fail to receive regulatory approval for many reasons, including the following:

- the FDA, EMA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA, EMA or other comparable foreign regulatory authorities may determine that OP-1250 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, EMA 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 OP-1250 may not be sufficient to support the submission of a NDA, or other submission or to obtain regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA, EMA or other comparable foreign regulatory authorities that OP-1250's risk-benefit ratio for its proposed indication is acceptable;
- the FDA, EMA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.
- This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market OP-1250, which would significantly harm our business, financial condition, results of operations and prospects.

In addition, even if we obtain approval of OP-1250 for a lead indication, regulatory authorities may not approve OP-1250 for other indications, may impose significant limitations in the form of narrow indications, warnings, or a Risk Evaluation and Mitigation Strategy, or REMS. Certain regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials or may approve OP-1250 with a label that does not include the labeling claims necessary or desirable for successful. In addition, regulatory authorities in certain countries may not approve the price we intend to charge for the product we develop. If we are unable to obtain regulatory approval of OP-1250, or if regulatory approval is limited, our business, financial condition, results of operation and prospects will be significantly harmed.

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

We may experience delays in clinical trials of OP-1250 or any future product candidate we may develop. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients, or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including delays related to:

- the FDA, EMA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;

- obtaining regulatory authorizations to commence a trial or reaching a consensus with regulatory authorities on trial design;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval from one or more institutional review boards, or IRBs;
- IRBs refusing to approve, suspending 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 candidate 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;
- delays in enrollment by subjects, or completion of the trial by subjects, due to the COVID-19 pandemic;
- subjects choosing an alternative treatment for the indication for which we are developing OP-1250, 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;
- 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 OP-1250 or any future product candidate we may develop or any of their components, including by order from the FDA, competent authorities of EU Member States or comparable foreign regulatory authorities due to violations of current good manufacturing practice, or cGMP, regulations or other applicable requirements, or infections or cross-contaminations of OP-1250 or any future product candidate we may develop in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices, or GCP, or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner; or

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

In addition, disruptions caused by the COVID 19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs 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 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 for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as we may do for OP-1250 or product candidates we may develop in the future, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

If we experience delays in the completion of, or termination of, any clinical trial of OP-1250 or any product candidates we may develop in the future, the commercial prospects of OP-1250 or any product candidates we may develop in the future will be harmed, and our ability to generate product revenues from OP-1250 or any product candidates we may develop in the future will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down OP-1250's or any product candidates we may develop in the future's development and approval process and jeopardize our ability to commence product sales and generate revenues.

In addition, many of the factors that cause, or lead to, termination 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 OP-1250 or any product candidates we may develop in the future. Any delays in our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize OP-1250 or any product candidates we may develop in the future and our competitors may be able to bring products to market before we do, and the commercial viability of OP-1250 or any product candidates we may develop in the future could be significantly reduced. Any of these occurrences may significantly harm our business, financial condition, results of operations and prospects.

Because we are pursuing a variety of target indications for OP-1250, 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 OP-1250, and we have expended, and plan to continue to expend, significant resources to pursue these and other indications for OP-1250. In addition, we 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, OP-1250 may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Even if OP-1250 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 OP-1250, such as boxed warnings or contraindications in labeling, or a REMS, 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 OP-1250 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 OP-1250 or similar approved products or product candidates in development by third parties; and
- the approval of other new therapies for the same indications.

If OP-1250 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 and 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 OP-1250, or any future product candidate we may develop, if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA, EMA 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.

As a result of the COVID-19 pandemic, we have faced risk that enrollment of patients in our clinical trials and maintaining patients in our ongoing clinical trials could be delayed or limited as our clinical trial sites limit their onsite staff or temporarily close as a result of the COVID-19 pandemic, and may continue to face these risks as the COVID-19 pandemic continues to evolve. In addition, if, for any reason, patients are unable to visit clinical trial sites for dosing or data collection purposes related to the COVID-19 pandemic or for other reasons, such factors could delay the anticipated readouts from our clinical trials and ultimately delay future regulatory submissions.

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 OP-1250, or any future product candidate we may develop, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' product candidates. Patient enrollment for any of our clinical trials may be affected by other factors, including:

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

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 OP -250 or any future product candidate we may develop and jeopardize our ability to obtain marketing approval for the sale of OP-1250 or any product candidate we may

develop in the future. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining enrollment of such patients in our clinical trials.

We intend to develop OP-1250, and may develop future product candidates, in combination with other therapies, which exposes us to additional risks.

We intend to develop OP-1250, and may develop other future product candidates, in combination with one or more other approved or unapproved therapies to treat cancer or other diseases. For example, in December 2021, we initiated a Phase 1b clinical trial of OP-1250 in a combination trial with a cyclin-dependent kinase 4 and 6 inhibitor, and we plan to initiate additional combinations trials of OP-1250 as part of combination therapy with independent arms investigating its potential with a cyclin-dependent kinase 4 and 6 inhibitor and with a phosphatidylinositol 3 kinase alpha inhibitor.

Even if OP-1250, or any future product candidate we develop, were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, EMA 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 OP-1250, or any future product candidate we may develop, are replaced as the standard of care for the indications we choose for OP-1250 or any future product candidate we may develop, the FDA, EMA 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 OP-1250 or future product candidates in combination with one or more cancer therapies that have not yet been approved for marketing by the FDA, EMA or comparable foreign regulatory authorities. We will not be able to market and sell OP-1250, or any future product candidate we may develop, in combination with an unapproved cancer therapy for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved cancer therapies face the same risks described with respect to OP-1250 currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA, EMA or comparable foreign regulatory approval.

If the FDA, EMA 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 OP-1250 or future product candidates we may develop, we may be unable to obtain approval of or market such combination therapy.

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

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

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

scope of our rights under them may be reduced and we might be unable to develop, manufacture or market any product that is licensed under these agreements.

The incidence and prevalence for target patient populations of OP-1250 are based on estimates and third-party sources. If the market opportunities for OP-1250, or any future product candidate we may develop, if and when approved, are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.

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

The incidence and prevalence for target patient populations of OP-1250 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 OP-1250, or any future product candidate we may develop, if and when approved, are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.

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

From time to time, we may publicly disclose preliminary or top-line data from our 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 agencies, 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, OP-1250 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 OP-1250, or product candidates we may develop in the future, our commercial opportunities will be negatively impacted.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products, product candidates and processes competitive with OP-1250. 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 OP-1250. 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, OP-1250 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 OP-1250 and any product candidate that we may develop in the future.

In particular, there is intense competition in the fields 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, 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.

If we are successful in developing OP-1250, it may compete against existing products and product candidates in development, to the extent any such product candidates are approved, for the treatment of estrogen receptor-positive, or ER+, breast cancer, including fulvestrant, marketed as FASLODEX® by AstraZeneca PLC and generic equivalents of FASLODEX® that are marketed or in development, giredestrant (GDC-9545) being developed by Roche Holding AG/Genentech, Inc., or Genentech, camizestrant (AZD9833) being developed by AstraZeneca PLC, amcenestrant (SAR439859) being developed by Sanofi S.A., LY3484356 being developed by Eli Lilly and Co., ZN-c5 being developed by Zentalis Pharmaceuticals, Inc., elacestrant (RAD1901) being developed by Radius Health, Inc., ARV 471 being developed by Arvinas, Inc., rintodestrant (G1T48) being developed by G1 Therapeutics, Inc., H3B 6545 being developed by H3 Biomedicines, a subsidiary of Eisai Co., Ltd., D-0502 being developed by InventisBio Co., Ltd., and lasofoxifene being developed by Sermonix Pharmaceuticals.

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, EMA 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, EMA 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 OP-1250 or other product candidates we may develop in the future achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. Technological advances or products developed by our competitors may render our technologies or OP-1250 or product candidates we may develop in the future obsolete, less competitive or not economical. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our product we may develop, if approved, would be adversely affected.

Changes in methods of OP-1250 manufacturing or formulation may result in additional costs or delay.

As OP-1250 progresses through nonclinical and clinical trials to 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 OP-1250 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 OP-1250 and jeopardize our ability to commercialize OP-1250, if approved, and generate revenue.

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

The availability and extent of coverage and adequate reimbursement by third-party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. If we obtain marketing approval of OP-1250, or any future product candidate we may develop, sales of such product will depend substantially, both in the United States and internationally, on the extent to which the costs of the product will be covered and reimbursed by third-party payors. If reimbursement is not available, or is available only at inadequate levels, we may not be able to successfully commercialize OP-1250 or any future product candidates we may develop. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, for example, principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, HHS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor's determination to provide

coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our product to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular products and requiring substitutions of generic products and/or biosimilars. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA- approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our product. Nonetheless, OP-1250 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 Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as OP-1250 or any future product candidates we may develop. In many countries, particularly the countries of the European Union, 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 OP-1250 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 OP-1250 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 OP-1250 or any future product candidates we may develop.

Government agencies promulgate regulations and guidelines directly applicable to us and to OP-1250 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 agencies 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 OP-1250 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 OP-1250 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 OP-1250 or any future product candidate we may develop.

OP-1250 is, and any product candidate we develop in the future will be, subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs. Rigorous 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 OP-1250 or any product candidate we may develop will progress through required clinical testing and obtain the regulatory approvals necessary for us to begin selling them.

We have not conducted, managed or completed large-scale or pivotal clinical trials nor managed the regulatory approval process with the FDA or any other regulatory authority. The time required to obtain approvals from the FDA and other regulatory authorities is unpredictable, and requires successful completion of extensive clinical trials which typically takes many years, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA, EMA or other comparable foreign regulatory authorities use when evaluating clinical trial data can, and often does, change during drug development, which makes it difficult to predict with any certainty how they will be applied. We may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, or changes in FDA, EMA or other comparable foreign regulatory authorities' policies during the period of drug development, clinical trials and FDA, EMA 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 developing and seeking approval. Furthermore, any regulatory approval to market a drug may be subject to significant limitations on the approved uses or indications for which we may market the drug or the labeling or other restrictions. In addition, the FDA has the authority to require a REMS as part of approving a NDA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. These requirements or restrictions might include limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may significantly limit the size of the market for the drug and affect reimbursement by third-party payors.

We may also become subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials and manufacturing of OP-1250. 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.

The withdrawal of the United Kingdom from the European Union may adversely impact our ability to obtain regulatory approvals of our product candidates in the United Kingdom, result in restrictions in the importation of our product candidates between the United Kingdom and the European Union, and may require us to incur additional expenses to commercialize our product candidates in the United Kingdom and the European Union.

Following the result of a referendum in 2016, the United Kingdom left the European Union on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the European Union, the United Kingdom was subject to a transition period until December 31, 2020, or the Transition Period, during which European Union rules continued to apply. A trade and cooperation agreement, or the Trade and Cooperation Agreement, that outlines the future trading relationship between the United Kingdom and the European Union provisionally applied from January 1, 2021, and formally entered into force on May 1, 2021.

Since a significant proportion of the regulatory framework in the United Kingdom applicable to our business and our product candidates is derived from European Union directives and regulations, Brexit has had, and will continue to have, a material impact upon the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the United Kingdom or the European Union, should any development or manufacturing of our product candidates take place in the United Kingdom.

Great Britain (made up of England, Scotland, and Wales) is no longer covered by the EMA's procedures for the grant of marketing authorizations (Northern Ireland will be covered by such procedures). A separate marketing authorization will be required to market drugs in Great Britain. Any delay in obtaining, or an inability to obtain, any marketing approvals in Great Britain, would delay or prevent us from commercializing our product candidates in Great Britain and restrict our ability to generate revenue and achieve and sustain profitability.

While the Trade and Cooperation Agreement provides for the tariff-free trade of medicinal products between the United Kingdom and the European Union there may be additional non-tariff costs to such trade which did not exist prior to the end of the Transition Period. Further, should the United Kingdom further diverge from the European Union from a regulatory perspective in relation to medicinal products, tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses (when compared to the position prior to the end of the Transition Period) to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the United Kingdom.

Orphan designation in Great Britain following Brexit is, unlike in the European Union, not available pre-marketing authorization. Applications for orphan designation are made at the same time as an application for a marketing authorization. The criteria to be granted an orphan drug designation or essentially identical to those in the European Union but based on the prevalence of the condition in Great Britain. It is therefore possible that conditions that were or would have been designated as orphan conditions in Great Britain prior to the end of the Transition Period are or would no longer be and that conditions that were not currently designated as orphan conditions in the European Union will be designated as such in Great Britain.

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 or other regulatory authority investigation of the safety and effectiveness of our product, our manufacturing processes

and facilities or our marketing programs. FDA, EMA 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 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 OP-1250, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could significantly harm our business, financial condition, results of operations and prospects.

OP-1250 and any future product candidates we develop may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could inhibit regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with the use of OP-1250 or any future product candidates we may develop. For example, during the Phase 1a portion of our Phase 1/2 clinical trial, three patients had grade 4 neutropenia attributed to study drug by the investigator, and two of these patients presented with fever and neutropenia. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by OP-1250 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, EMA or other comparable foreign regulatory authorities. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may significantly harm our business, financial condition, results of operations and prospects.

If OP-1250 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. OP-1250 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 agencies. In addition, if OP-1250 or any future product candidates we may develop, are used in combination with other therapies, OP-1250 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 OP-1250 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 OP-1250 or any future product candidates we may develop, but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses.

If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, competent authorities of EU Member States, other comparable regulatory authorities or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could significantly harm our business, financial condition, results of operations and prospects. Further, if OP-1250 obtains marketing approval, toxicities associated with OP-1250 and not seen during clinical testing may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether OP-1250 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 and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

We may choose to conduct international clinical trials in the future. The acceptance of study data by the FDA, EMA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (1) the data are applicable to the United States population and United States medical practice; (2) the trials are performed by clinical investigators of recognized competence and pursuant to current GCP requirements; and (3) the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including the adequacy of the patient population studied and statistical powering, must be met. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA or any applicable foreign regulatory authority will accept data from trials conducted outside of its applicable jurisdiction. If the FDA, EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in OP-1250 or any future product candidates we may develop not receiving approval for commercialization in the applicable jurisdiction.

Obtaining and maintaining regulatory approval of OP-1250, 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 OP-1250, or any product candidate we develop in the future, in other jurisdictions.

Obtaining and maintaining regulatory approval of OP-1250, 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, EMA 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 OP-1250, or any product candidate we develop in the future, will be harmed.

Even if OP-1250, 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 OP-1250, 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 OP-1250, 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, EMA or applicable foreign regulatory authorities approve OP-1250 or any product candidate we develop in the future, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for OP-1250 will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with cGMPs and GCP for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency 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 agency 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, EMA and other comparable 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 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 OP-1250, or any product candidate we may develop in the future, and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of OP-1250 or any product candidate we may develop in the future. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

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

If OP-1250 or any future product candidate we may develop is approved for marketing, and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as OP-1250 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 agencies as reflected in the product's approved labeling. If we receive marketing approval for OP-1250 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 OP-1250 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, applicable foreign regulatory authorities, the U.S. Securities and Exchange Commission, or the SEC, and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies 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 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 and accept the payment of user fees, and statutory, regulatory, and policy changes, and other events that may otherwise affect the FDA, EMA or any applicable foreign regulatory authority's ability to perform routine functions. Average review times at the agencies have fluctuated in recent years as a result and could be delated by the COVID 19 pandemic or other factors. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. Separately, in response to the COVID 19 pandemic, in March 2020, the FDA announced its intention to postpone most inspections of foreign and domestic manufacturing facilities and in July 2020 only restarted

inspections on a risk-based basis. Regulatory authorities outside the United States have adopted similar restrictions or other policy measures in response to the COVID 19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We may attempt to secure approval from the FDA, EMA 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 accelerated approval from the FDA, EMA or comparable foreign regulatory authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA, EMA or comparable foreign regulatory authorities may seek to withdraw any accelerated approval.

We may in the future seek an accelerated approval for OP-1250 or future product candidates we may develop. 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 verity 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 OP-1250, 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 OP-1250, 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 OP-1250 would result in a longer time period to commercialization of such product candidate, could increase the cost of development of OP-1250 and could harm our competitive position in the marketplace.

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

Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of OP-1250 or any future product candidates we may develop. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

For example, in March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and continues to significantly impact the U.S. pharmaceutical industry. There have been executive, judicial and Congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have passed. On December 22, 2017, President Trump signed into law federal tax legislation commonly referred to as the Tax Cuts and Jobs Act, or the Tax Act, which included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” On June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect until 2031, except for a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic, unless additional congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug’s average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In addition, Congress is considering additional health reform measures. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on potential customers for our drugs, if approved, and accordingly, our business.

Moreover, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

For example, at the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempted to implement several of the administration's proposals. The FDA concurrently released a final rule and guidance in September 2020 implementing a portion of the importation executive order providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The implementation of this rule has been delayed until January 1, 2027. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries. The Most Favored Nation regulations mandate participation by identified Medicare Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. As a result of litigation challenging the Most Favored Nation model. On December 27, 2021, CMS published a final rule that rescinds the Most Favored Nation model interim final rule. Further, in July 2021, the Biden administration released an executive order that included multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. 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.

We expect that the ACA, 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 OP-1250 or any future product candidates we may develop. It is possible that additional governmental action is taken in response to the COVID 19 pandemic.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of OP-1250 or any future product candidates we may develop, if any, may be.

Our relationships with healthcare professionals, clinical investigators, CROs and third party payors in connection with our current and future business activities may be subject to federal and state 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 candidate for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly

applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our product for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

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

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

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

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

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

- analogous state and foreign laws and regulations, such as state 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.

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

State and international laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. For instance, the collection and use of health data in the European Union is governed by the General Data Protection Regulation, or the GDPR, which extends the enforcement of European Union data protection law to non-European Union entities under certain conditions, tightens existing European Union data protection principles, creates new obligations for companies and new rights for individuals. In particular, the GDPR includes obligations and restrictions concerning the consent and rights of individuals to whom the personal data relates, the transfer of personal data out of the European Economic Area, or EEA, or the United Kingdom, security breach notifications and the security and confidentiality of personal data. Further, the UK has implemented legislation similar to the GDPR, including the UK Data Protection Act and legislation similar to the GDPR referred to as the UK GDPR, which provides for fines of up to the greater of 17.5 million British Pounds or 4% of a company's worldwide turnover, whichever is higher.

In addition to introducing new data protection requirements in the EEA, the GDPR also established potential fines for noncompliant companies. Failure to comply with the GDPR may result in substantial fines up to the greater of €20 million or 4% of annual global revenue and other administrative penalties. Such fines are in addition to any civil litigation claims by data subjects. EEA data protection authorities may interpret the GDPR and national laws differently and impose additional requirements, which contributes to the complexity of processing personal data in or from the EEA or United Kingdom. Guidance on implementation and compliance practices is often updated or otherwise revised. The GDPR may increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the GDPR. This may be onerous and if our efforts to comply with the GDPR or other applicable European Union laws and regulations are not successful, it could adversely affect our business in the European Union.

European data protection laws also generally prohibit the transfer of personal data from Europe, including the EEA, United Kingdom and Switzerland, to the United States and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. One of the primary safeguards used for transfers of personal data from the European Union to the United States, namely, the Privacy Shield framework administered by the U.S. Department of Commerce, was invalidated by a decision of the European Union's highest court. The European Commission, however, released a set of "Standard Contractual Clauses" in June 2021 that are designed to be a valid mechanism by which entities can transfer personal data out of the EEA to jurisdictions that the European Commission has not found to provide an adequate level of protection. The Standard Contractual Clauses, however, require parties that rely upon that legal mechanism to comply with additional obligations, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at-issue personal data. Moreover, due to potential legal challenges, there exists some uncertainty regarding whether the Standard Contractual Clauses will remain a valid mechanism for transfers of personal data out of the EEA.

Further, the vote in the United Kingdom in favor of exiting the European Union, referred to as Brexit, has complicated data protection regulation in the United Kingdom. In particular, as of January 1, 2021, the GDPR has been converted into United Kingdom law and the United Kingdom is now a "third country" under the GDPR. Pursuant to the Trade and Cooperation Agreement, which went into effect on January 1, 2021, the United Kingdom and European Union agreed to a specified period during which the United Kingdom will be treated like a European Union member state in relation to transfers of personal data to the United Kingdom. On June 28, 2021, the European Commission announced a decision of "adequacy" concluding that the UK ensures an equivalent level of data protection to the GDPR, which provides some relief regarding the legality of continued personal data flows from the EEA to the UK. Some uncertainty remains, however, as this adequacy determination must be renewed after four years and may be modified or revoked in the interim. We cannot fully predict how the Data Protection Act, the UK GDPR, and other UK data protection laws or regulations may develop in the medium to longer term nor the effects of divergent laws and guidance regarding how data transfers to and from the UK will be regulated. In addition, as of January 1, 2021, the United Kingdom Information Commissioner's Office is not able to be our 'lead supervisory authority' in respect of any 'cross border processing' for the purposes of the GDPR. In the event that we are unable to, or do not, designate a

lead supervisory authority in an EEA member state, we would not be able to benefit from the GDPR's 'one stop shop' mechanism. Amongst other things, this would mean that, in the event of a violation of the GDPR affecting data subjects across the United Kingdom and the EEA, we could be investigated by, and ultimately fined by the United Kingdom Information Commissioner's Office and the supervisory authority in each and every EEA member state where data subjects have been affected by such violation.

In the United States, numerous federal and state laws and regulations, including state personal information laws, state data breach notification laws, and federal and state consumer protection laws and regulations govern the collection, use, disclosure and protection of personal information. For example, sthe California Consumer Privacy Act, or CCPA, went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information of consumers or households. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact certain of our business activities and may increase our compliance costs and potential liability.

Additionally, California voters approved a new privacy law, the California Privacy Rights Act, or CPRA, in the November 3, 2020 election. Effective starting on January 1, 2023, the CPRA will significantly modify the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. In addition, other states have enacted or proposed data privacy laws. For example, , Virginia passed the Consumer Data Protection Act, or the VCDPA, effective January 1, 2023;, Colorado recently passed the Privacy Rights Act, or the CPA, effective July 1, 2023; Connecticut passed the Data Privacy Act, or CDPA, effective July 1, 2023; and Utah recently passed the Consumer Privacy Act, or the UCPA, effective December 31, 2023. These laws demonstrate our vulnerability to the evolving regulatory environment related to personal information and make it difficult to predict the impact of such laws on our business or operations. The CPA and CDPA are similar to the CCPA and CPRA but 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.

In addition to the foregoing, any breach of privacy laws or data security laws, particularly resulting in a significant security incident or breach involving the misappropriation, loss or other unauthorized use or disclosure of sensitive or confidential patient or consumer information, could have a material adverse effect on our business, reputation and financial condition. As a data controller (under the GDPR) or business (under the CCPA), we will be accountable for any third-party service providers we engage to process personal data on our behalf, including our CROs. We attempt to mitigate the associated risks but there is no assurance that privacy and security-related safeguards will protect us from all risks associated with the third-party processing, storage and transmission of such information.

New legislation proposed or enacted in Illinois, Massachusetts, Nevada, New Jersey, New York, Rhode Island, Washington and other states, and a proposed right to privacy amendment to the Vermont Constitution, imposes, or has the potential to impose, additional obligations on companies that process confidential, sensitive and personal information, and will continue to shape the data privacy environment nationally. State laws are changing rapidly and there is discussion in Congress of a new federal data protection and privacy law to which we would become subject if it is enacted. All of these evolving compliance and operational requirements, including the requirement to comply with GDPR, CCPA, CPRA, VDCPA, CDPA, CPA, UCPA or other laws, regulations, amendments to or re-interpretations of existing laws and regulations, and contractual or other obligations relating to privacy, data protection, data transfers, data localization, or information security may impose significant costs that are likely to increase over time, may require us to modify our data processing practices and policies, divert resources from other initiatives and projects, modify our data practices and policies, restrict our business operations, and could restrict the way products and services involving data are

offered, all of which could significantly harm our business, financial condition, results of operations and prospects. Further, certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to confidential, sensitive and personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts. Any actual or perceived failure by us to comply with these laws, regulations, or other obligations may lead to significant fines, penalties, regulatory investigations, lawsuits, significant costs for remediation, damage to our reputation, or other liabilities.

Many statutory requirements involving privacy and security, both in the United States and abroad, include obligations for companies to notify individuals of security breaches involving certain personal information, which could result from breaches experienced by us or our third-party service providers. For example, laws in all 50 U.S. states and the District of Columbia require businesses to provide notice to consumers whose personal information has been disclosed as a result of a data breach. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. Moreover, states have been frequently amending existing laws, requiring attention to changing regulatory requirements. We also may be contractually required to notify customers or other counterparties of a security breach. Although we may have contractual protections with our third-party service providers, contractors and consultants, any actual or perceived security breach could harm our reputation and brand, expose us to potential liability or require us to expend significant resources on data security and in responding to any such actual or perceived breach. Any contractual protections we may have from our third-party service providers, contractors or consultants may not be sufficient to adequately protect us from any such liabilities and losses, and we may be unable to enforce any such contractual protections.

We expect that there will continue to be newly proposed health-related, privacy, and security laws and regulations, and we cannot yet determine the impact such future laws, regulations and standards may have on our business. New laws, amendments to or re-interpretations of existing laws, regulations, standards and other obligations may require us to incur additional costs and restrict our business operations, though our efforts to comply with the evolving data protection rules may be unsuccessful. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy regulations may differ from country to country, and may vary based on whether testing is performed in the United States or in the local country and our operations or business practices may not comply with these regulations in each country.

In addition to the possibility of fines, lawsuits, regulatory investigations, public censure, other claims and penalties, and significant costs for remediation and damage to our reputation, we could be materially and adversely affected if legislation or regulations are expanded to require changes in our data processing practices and policies or if governing jurisdictions interpret or implement their legislation or regulations in ways that negatively impact our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Any inability to adequately address data privacy or security-related concerns, even if unfounded, or to comply with applicable laws, regulations, standards and other obligations relating to data privacy and security, could result in additional cost and liability to us, harm our reputation and brand, damage our relationships with customers and have a material adverse effect on our business.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve on-going substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, 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.

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 regulations, provide accurate information to the FDA, comply with federal and state health care fraud and abuse laws and regulations, 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, 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 candidate on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed or become more expensive.

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

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

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

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

The COVID-19 pandemic could adversely impact our business, including our nonclinical studies and clinical trials.

The COVID-19 pandemic and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the spread of COVID-19, we closed our offices with our administrative employees working outside of our offices and limited the number of staff in any given research and development laboratory. In October 2021, we re-opened our offices to administrative employees, however due to the resurgence of cases relating to the spread of the Delta and Omicron variants, we have continued to limit access to our offices and we may close our offices again in the future as the COVID-19 pandemic continues to evolve. As a result of the COVID 19 pandemic, we experienced some delays in setting up our current Phase 1/2 clinical trial and in clinical site initiation, including delays in recruiting clinical site investigators and clinical site staff, which we may experience again in the future. Additionally, we may experience further disruptions that could severely impact our business, nonclinical studies and clinical trials, including:

- delays or difficulties in enrolling and retaining patients in our clinical trials;
- difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to the COVID-19 pandemic, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of OP-1250 from our CMOs, due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- interruptions in nonclinical studies due to restricted or limited operations at our laboratory facility;
- limitations on employee resources that would otherwise be focused on the conduct of our nonclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- interruption or delays to our sourced discovery and clinical activities.

The COVID 19 pandemic continues to evolve. The extent to which the outbreak impacts our business, nonclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

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 OP-1250 or any other product candidate will be limited and the potential for successfully growing our business will be harmed.

If we are unable to establish sales or marketing capabilities or enter into agreements with third parties to sell or market OP-1250 or any product candidate we may develop in the future, we may not be able to successfully sell or market OP-1250 or any future product candidate we may develop that obtain regulatory approval.

We currently do not have, and have never had, a marketing or sales team. In order to commercialize any product candidates, if approved, we must build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell or market OP-1250 or any future product candidate we may develop. We may not be successful in accomplishing these required tasks.

Establishing an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize OP-1250 or any product candidate we may develop in the future will be expensive and time-consuming, and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of OP-1250 or any product candidate we may develop in the future that we obtain approval to market, if we do not have arrangements in place with third parties to provide such services on our behalf. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration. If we are unable to enter into such arrangements when needed, on acceptable terms, or at all, we may not be able to successfully commercialize OP-1250 or any product candidate we may develop in the future which may receive regulatory approval or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

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

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

Factors that may affect our ability to commercialize OP-1250, or any future product candidate we may develop, on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe OP-1250 or any future product candidates we may develop and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of OP-1250 or any future product candidate we may develop. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of OP-1250 or any future product candidate we may develop, we may not generate revenues from such product candidate or be able to reach or sustain profitability.

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

As of June 30, 2022, we had 75 employees, 72 of whom were full-time, including 42 employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, and as we transition into operating as a public company, 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 agencies' review process for OP-1250 and any other future product candidates we may develop, while complying with any contractual obligations to contractors and other third parties we may have; and
- improving our operational, financial and management controls, reporting systems and procedures.

In addition, we expect to be conducting multiple clinical trials of OP-1250 for several different indications 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, OP-1250 and any other future product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of clinical development and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third-party service providers is compromised for any reason, our

clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of OP-1250 and any other future product candidates we may develop or otherwise advance our business. We cannot assure you that we will be able to manage our existing third-party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize OP-1250 and any other future product candidates we may develop and, accordingly, may not achieve our research, development and commercialization goals.

Our internal computer systems, or those of any of our CROs, manufacturers, other contractors, consultants, collaborators, potential future collaborators, or other third parties (including service providers in our supply chain) may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data, or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.

Despite the implementation of preventative and detective security measures, our internal computer systems and those of our current and any future CROs and other contractors, consultants, collaborators and third-party service providers that process our sensitive information (including personal information and personally identifiable data), are vulnerable to damage or interruption from a variety of sources, including computer viruses, unauthorized access, intentional or accidental acts or omissions by those with authorized access, natural disasters, terrorism, war, telecommunication and electrical failure, and cybersecurity threats (including the deployment of harmful malware, ransomware, denial-of-service attacks, supply chain attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information). The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations, or hostile foreign governments or agencies.

If such an event were to occur or were alleged to have occurred and cause interruptions in our operations or result in the unauthorized acquisition of or access to personally identifiable information or individually identifiable health information (violating certain privacy laws, as applicable, such as HIPAA, CCPA, HITECH and GDPR), it could result in a material disruption or termination of our drug discovery and development programs and our business operations, whether due to a loss of our trade secrets, personal information, or other similar disruptions. Some of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Notifications and follow-up actions related to a security breach could impact our reputation, cause us to incur significant costs, including legal expenses and remediation costs and divert resources from other efforts. For example, in November 2021, we were alerted to falsified information circulating on social media relating to our planned poster presentation for the Phase 1 dose-escalation portion of the ongoing Phase 1/2 clinical trial of OP-1250 at the San Antonio Breast Cancer Symposium. Additionally, the loss of clinical trial data from completed or future clinical trials could result in delays or revocation of our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. We also rely on third parties to manufacture OP-1250, and similar events relating to their computer systems could also have a material adverse effect on our business. We may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, to develop and implement protections to prevent future events of this nature from occurring, and to address other related concerns or issues. To the extent that any disruption or security breach were to result in a loss of, or damage

to, our data, or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations, the further development and commercialization of OP-1250 could be delayed, and we could be subject to significant fines or penalties for any noncompliance with certain state, federal and/or international privacy and security laws.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure or security breach. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

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

We intend to seek approval to market OP-1250 in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for OP-1250, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of drugs is subject to governmental control and other market regulations which could put pressure on the pricing and usage of OP-1250. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of OP-1250 will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for OP-1250 and may be affected by existing and future healthcare reform measures.

Much like the federal Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of EU Member States, such as the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In addition, in most foreign countries, including a number of EU Member States, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. A 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. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of OP-1250 to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow favorable reimbursement and pricing arrangements for our product. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our product is unavailable or limited in scope or amount, our potential revenues from sales and the potential profitability of OP-1250 in those countries would be negatively affected.

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 (including, for example, the outbreak of COVID 19), 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 OP-1250 or any future product candidates we may develop could be disrupted if our operations or those of our suppliers are affected by man-made or natural disasters or other business interruptions. Our corporate headquarters are located in California near major earthquake faults and fire zones. The ultimate impact on us, our significant suppliers and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and business could suffer in the event of a major earthquake, fire or other natural disaster.

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

Our net operating loss, or NOL, carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 taxable years under applicable U.S. federal tax law. Under the Tax Act, as modified by the Coronavirus Aid, Relief, and Economic Security, or CARES Act, federal NOLs generated in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs may be limited to 80% of current year taxable income for tax years beginning on or after December 31, 2020. It is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act.

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

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

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Act enacted many significant changes to the U.S. tax laws and proposals have recently been made in Congress (which have not yet been enacted) to make other tax law changes that could have a material adverse impact on us. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act or any newly enacted federal tax legislation.

A variety of risks associated with marketing OP-1250 or any future product candidate we may develop internationally could significantly harm our business, financial condition, results of operations and prospects.

We plan to seek regulatory approval of OP-1250 or any future product candidates we may develop outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

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

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

Risks related to our intellectual property

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

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection in the United States and other countries for OP-1250 and any future product candidates that we may develop and technologies related to their various uses. We generally seek to protect our proprietary position by, among other things, filing patent applications in the United States and abroad related to OP-1250, our proprietary technologies, and their manufacture and uses that are important to our business, as well as inventions and improvements that are important to the development and implementation of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our

proprietary and intellectual property position. We may also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending applications from third parties. If we or our potential licensors are unable to obtain or maintain patent protection with respect to OP-1250, proprietary technologies and their uses, our business, financial condition, results of operations and prospects could be significantly harmed.

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

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

Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. Thus, the degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect the intellectual property rights relating to OP-1250 or any future product candidates we may develop could significantly harm our business, financial condition, results of operations and prospects.

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

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting OP-1250 or any future product candidates we may develop by obtaining and defending patents. These risks and uncertainties include the following:

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

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

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

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

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

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

The patent prosecution process is also expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection, for example, if patentable aspects are publicly disclosed, by us or a third party, such as by public use, sale or offer for sale, or publication.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Further, although we require our employees, commercial contractors, and certain consultants and investigators to enter into invention assignment agreements that grant us ownership of any discoveries or inventions made by them while in our employ, we cannot guarantee that we have entered into such agreements with each party, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach such agreements and claim ownership in intellectual property that we believe is owned by us. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our owned or any licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

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

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

The patent positions of biopharmaceutical companies generally are highly uncertain, involve complex legal and factual questions for which important legal principles remain unsolved and have been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect OP-1250 or which effectively prevent others from commercializing competitive technologies and product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted after issuance. Legal standards relating to valid and enforceable claim scope are unsettled in the United States and elsewhere and disputes challenging or re-defining scope are common in the biopharmaceutical industry. Even if patent applications we own or in-license currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether OP-1250 or any future product candidates we may develop will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or

alternative technologies or products in a non-infringing manner which could significantly harm our business, financial condition, results of operations and prospects.

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

The process by which patent applications are examined and considered for issuance as patents involves consideration by the relevant patent office of "prior art" relative to the invented technology. Different countries have different rules about what information or events can be considered "prior art," and different requirements regarding when a patent application must be filed relative to any particular piece of potential prior art. Moreover, legal decisions can re-interpret or change whether particular information or events are considered to be "prior art." Still further, in the United States, patent applicants are required to notify the USPTO of any material "prior art" of which they are aware for the patent examiner to consider in addition to independent searches that the patent examiner is required to do. Also, in the United States and certain other jurisdictions, third parties are entitled to submit prior art to patent offices for consideration during examination.

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

We may be subject to a third-party pre-issuance submission of prior art to the USPTO or other jurisdictions, or become involved in post-grant challenges such as opposition, derivation, revocation, reexamination, post-grant review, or PGR, and inter partes review, or IPR, or other similar proceedings, or in litigation, challenging our patent rights, including by challenging the validity or the claim of priority of our patents. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize OP-1250 or any future product candidates we may develop and compete directly with us, without payment to us. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of OP-1250 or any future product candidates we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, including art of which we were unaware, and art which was not raised during prosecution of any of our patent applications. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technology or platform, or any product candidates that we may develop. Such a loss of patent protection would significantly impact our business, financial condition, results of operations and prospects. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future product candidates or could embolden competitors to launch products or take other steps that could disadvantage us in the marketplace or draw us into additional expensive and time consuming disputes. Should any of these events occur, it could significantly harm our business, financial condition, results of operations and prospects.

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

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

- we may not be able to detect infringement of our issued patents;

- others may be able to develop products that are similar to OP-1250, or any future product candidates we may develop, but that are not covered by the claims of the patents that we may in-license in the future or own;
- our competitors may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell OP-1250 or any future product candidates we may develop;
- we, or our current or future collaborators or license partners, might not have been the first to make the inventions covered by the issued patents or patent application that we may in-license in the future or own;
- we, or our current or future collaborators or license partners, might be found not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that the pending patent applications we may in-license in the future or own will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate our patents, or parts of our patents, for which we are not aware;
- issued patents that we hold rights to may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- issued patents may not have sufficient term or geographic scope to provide meaningful protection;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent in order to maintain certain trade secrets, and a third party may subsequently file a patent covering such intellectual property.

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

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

Our commercial success depends in part on avoiding infringement, misappropriation or other violations of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe, misappropriate or otherwise violate patents or other intellectual property rights owned or controlled by third parties. A finding by a court or administrative body that we infringe the claims of issued patents owned by third parties could preclude us from commercializing OP-1250 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 OP-1250 or any future product candidates we may develop and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, and proceedings, such as oppositions, reexaminations, IPR proceedings and PGR proceedings, before the USPTO and/or corresponding foreign patent offices. In addition, many companies in intellectual property-dependent industries, including the biopharmaceutical industry, have employed intellectual property litigation as a means to gain an advantage over their competitors. Numerous third-party U.S. and foreign issued patents and pending patent applications may exist in the fields in which we are developing OP-1250 or any future product candidates we may develop. There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of OP-1250 or any future product candidates we may develop. For example, we are aware of certain third-party patent applications and patents in the United States and abroad that include disclosure of chemical structures sharing certain similarities with OP-1250. It is possible that one or more of such third parties could pursue patent claims or assert patent claims that allegedly encompass OP-1250.

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

As the biopharmaceutical industry expands and more patents are issued, the risk increases that OP-1250, or any future product candidates we may develop, may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published, we may be unaware of third-party patents that may be infringed by commercialization of OP-1250, or any future product candidates we may develop, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently-pending patent applications that may later result in issued patents that OP-1250 or any future product candidates we may develop may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. There is also no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Still further, we cannot rely on our experience that third parties have not so far alleged that we infringe their patent rights, as provisions of U.S. patent laws provide a safe harbor from patent infringement for therapeutic products under clinical development. If and when we submit an NDA that safe harbor will expire.

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

- result in costly litigation that may cause negative publicity;
- cause development delays;

- prevent us from commercializing OP-1250 or any future product candidates we may develop;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Any patent-related legal action against us claiming damages or seeking to enjoin commercial activities relating to our products, or processes could subject us to significant liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or market OP-1250 or any future product candidates we may develop. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or a future strategic partner were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign OP-1250 or any future product candidates we may develop processes to avoid infringement, if necessary.

An adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing OP-1250 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 OP-1250 and future product candidates and technologies.

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

We may not be successful in obtaining or maintaining necessary rights from third parties for that we identify as necessary for OP-1250 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 OP-1250, it is possible that third parties may have blocking patents that prevent us from marketing, manufacturing or commercializing our own patented products and practicing our own patented technology.

We may be unsuccessful in acquiring or in-licensing compositions, methods of use, processes, or other intellectual property rights from third parties that we identify as necessary for practicing inventions claimed by our patents, including the manufacture, sale and use of OP-1250 and any future product candidates we may develop. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to

assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could significantly harm our business, financial condition, results of operations and prospects.

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

Competitors or other third parties may infringe, misappropriate or otherwise violate our intellectual property rights. To prevent infringement or unauthorized use, we may be required to file infringement or other intellectual property claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we may in-license in the future or own is not valid, is unenforceable, and/or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our owned patents or future in-licensed patents do not cover the technology in question. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at OP-1250 or any future product candidates we may develop, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, non-enablement, or obviousness-type double patenting. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

The outcome following legal assertions of invalidity and/or unenforceability is unpredictable, and prior art could render our patent invalid. There is no assurance that all potentially relevant prior art relating to our patent and patent applications has been found. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patent and patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim.

If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose at least part, and perhaps all, of the patent protection on such product candidate. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Such a loss of patent protection would significantly harm our business, financial condition, results of operations and prospects.

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

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

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

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

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

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

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

Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring OP-1250 or any future product candidates to market. Should any of these events occur, it could significantly harm our business, financial condition, results of operations and prospects.

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

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy- Smith Act, the United States transitioned in March 2013 to a “first inventor to file” system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013 but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we may not be certain that we or our licensors are the first to either (1) file any patent application related to OP-1250 or any future product candidate we may develop or (2) invent any of the inventions claimed in the patents or patent applications.

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

Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications or those of our licensors and the enforcement or defense of our issued patents or those of our licensors, all of which could significantly harm our business, financial condition, results of operations and prospects.

Changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect OP-1250 or any future product candidates we may develop.

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

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

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

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

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

Patent terms may be inadequate to protect our competitive position on OP-1250 or any future product candidates we may develop for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but there can be no assurance that any such extensions will be obtained, and the life of a patent, and the protection it affords, is limited. Even if patents covering OP-1250 or any future product candidates we may develop are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

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

If we do not obtain patent term extension for OP-1250 or any future product candidates we may develop, our business, financial condition, results of operations and prospects may be significantly harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of OP-1250 or any future product candidates we may develop, one or more of our U.S. patents or those of our licensors may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch- Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of OP-1250 or any future product candidates we may develop. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be significantly harmed. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and nonclinical data and launch their product earlier than might otherwise be the case.

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

Filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we will not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or

importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These infringing products may compete with OP-1250 or any future product candidates we may develop, without any available recourse.

The laws of some other countries do not protect intellectual property rights to the same extent as the laws of the United States. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biopharmaceuticals. As a result, many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. Because the legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceutical products, it could be difficult for us to stop the infringement, misappropriation or violation of our patents or our licensors' patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our intellectual property and other proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents or the patents of our licensors at risk of being invalidated or interpreted narrowly, could put our patent applications or the patent applications of our licensors at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

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

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

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

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business, financial condition, results of operations and prospects may be significantly harmed. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could significantly harm our business, financial condition, results of operations and prospects.

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

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

Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized. Any of the foregoing could significantly harm our business, financial condition, results of operations and prospects.

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

We have entered into and may enter in the future into non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, potential partners, lessees of shared multi-company property and other third parties. Many of our employees and consultants were previously employed at, or may have previously provided or may be currently providing consulting services to, other biopharmaceutical companies, including

our competitors or potential competitors. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may become subject to litigation where a third party asserts that we or our employees or consultants inadvertently or otherwise breached the agreements and used or disclosed trade secrets or other information proprietary to the third parties. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing OP-1250 or any future product candidates or technologies we may develop. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts, and cause us to lose valuable intellectual property rights or personnel, which could significantly harm our business, financial condition, results of operations and prospects. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

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

Our rights to develop and commercialize our technology and product candidate 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 OP-1250 or any future product candidates we may develop. These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in our licenses.

If we fail to comply with our obligations under any such license agreements, including obligations to make various milestone payments and royalty payments and other obligations, the licensor may have the right to terminate the license. If these agreements are terminated, we could lose intellectual property rights that are important to our business, be liable for any damages to such licensors or be prevented from developing and commercializing our product candidates, and competitors could have the freedom to seek regulatory approval of, and to market, products identical to ours. Termination of these agreements or reduction or elimination of our rights under these agreements may also result in our being required to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, or impede, delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our product candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering the technology that we license from third parties. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business, including the payment of all applicable fees for patents covering our product candidates. If our licensors fail to prosecute, maintain, enforce and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or

eliminated, and our right to develop and commercialize any of our products that are subject of such licensed rights could be adversely affected. Further, we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control the prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by the actions or inactions of our licensees, our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

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

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

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

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

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

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

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

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

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

Risks related to our dependence on third parties

We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct certain aspects of our 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

OP-1250 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 OP-1250 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 or state 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 OP-1250 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 OP-1250, 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 OP-1250. As a result, our results of operations and the commercial prospects for OP-1250 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.

The COVID 19 pandemic and government measures taken in response have also had a significant impact on our CROs, and we expect that they will face further disruption which may affect our ability to initiate and complete our nonclinical studies and clinical trials.

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 OP-1250 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 OP-1250 or other drugs necessary for the development or commercialization of OP-1250 or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently have the infrastructure or internal capability to manufacture supplies of OP-1250 for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of OP-1250 for nonclinical studies and clinical trials under the guidance of members of our organization. We do not have long-term supply agreements for OP-1250. Furthermore, the raw materials for OP-1250 are sourced, in some cases, from a single-source supplier. If we were to experience an unexpected loss of supply of OP-1250 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. For example, the extent to which the COVID 19 pandemic impacts our ability to procure sufficient supplies for the development of OP-1250 in the future will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain COVID 19 or treat its effects.

We expect to continue to rely on third-party manufacturers for the commercial supply of OP-1250, 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 OP-1250 according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over OP-1250 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 (including, for example, the ongoing COVID-19 pandemic;
- 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 OP-1250 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 do not have 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, EMA or others, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of OP-1250, 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 OP-1250, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of OP-1250 or other drugs necessary for the development or commercialization of OP-1250 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 OP-1250 are unable to produce sufficient quantities for clinical trials or for commercialization of OP-1250, 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 planned Phase 1b clinical trial of OP-1250 in combination with KISQALI® (ribociclib) or PIQRAY® (alpelisib), or the Novartis Study Drugs, in patients with metastatic ER+ breast cancer, we entered into a Clinical Collaboration and Supply Agreement with Novartis Institutes for BioMedical Research, Inc., or Novartis, or the Novartis Agreement. Under the terms of the Novartis Agreement, Novartis is providing KISQALI® (ribociclib) and PIQRAY® (alpelisib) for the clinical trial. If Novartis is unable to timely manufacture or provide KISQALI® (ribociclib) or PIQRAY® (alpelisib), or if the Novartis Agreement terminates and we are unable to obtain KISQALI® (ribociclib) or PIQRAY® (alpelisib) on the current terms, our planned Phase 1b clinical trial may be delayed and the cost to us to conduct this trial may significantly increase, which would significantly harm our business, financial condition, results of operations and prospects. For a description of the Novartis Agreement, see the section titled “Business - Clinical Trial Collaboration and Supply Agreement with Novartis” in our Annual Report on Form 10-K.

Our current and anticipated future dependence upon others for the manufacture of OP-1250 or other drugs necessary for the development or commercialization of OP-1250 may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

The manufacture of drugs is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of OP-1250 for clinical trials or our product for patients, if approved, could be delayed or prevented.

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

or closure of product facilities due to possible contamination. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization as a result of these challenges, or otherwise, our development and commercialization efforts would be impaired, which would significantly harm our business, financial condition, results of operations and prospects.

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

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

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

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

We have entered into collaborations with third parties for the development and commercialization of OP-1250. If those collaborations are not successful, we may not be able to capitalize on the market potential of OP-1250.

We have third-party collaborators for the development and commercialization of OP-1250. Our likely collaborators for any future collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies.

We have, and will likely continue to have, limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of OP-1250. 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 OP-1250 could pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;

- collaborators may deemphasize or not pursue development and commercialization of OP-1250 or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;

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

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with OP-1250 if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;

- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;

- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of OP-1250 or that result in costly litigation or arbitration that diverts management attention and resources;

- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;

- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all; and

- if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our drug development or commercialization program could be delayed, diminished or terminated.

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

Our drug development programs and the potential commercialization of OP-1250 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, EMA 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 OP-1250 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 OP-1250 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. 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 Annual Report, these factors include:

- the timing and results of nonclinical studies and clinical trials of OP-1250 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 candidate or our competitors' products;
- actual or anticipated changes in our growth rate relative to our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the pharmaceutical and biotechnology sector;
- changes in the structure of healthcare payment systems;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders; and
- general economic, industry and market conditions.

In addition, the trading prices for common stock of other biopharmaceutical companies have been highly volatile as a result of factors unrelated to the specific company or its technology, as well as due to the COVID 19 pandemic. The COVID 19 pandemic continues to rapidly evolve and the extent to which it may impact our business, nonclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

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.

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 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 OP-1250 or future development programs;
- timing and status of enrollment for our clinical trials;
- impacts from the COVID-19 pandemic 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 OP-1250 or any future product candidate we may develop receive regulatory approval, the timing and terms of such approval and market acceptance and demand for such product candidates;

- the timing and cost to establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with current or future collaborators;

- regulatory developments affecting OP-1250 or any future product candidate we may develop or those of our competitors; and

- changes in general market and economic conditions.

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

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

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

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

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

As of June 30, 2022, we had 40,401,626 shares of common stock outstanding. Shares issued upon the exercise of stock options and warrants outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, and Rules 144 and 701 under the Securities Act.

Moreover, certain holders of shares of our common stock, have rights, subject to certain conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or our other stockholders. 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 OP-1250 or future product candidates we may develop on unfavorable terms to us.

We may seek additional capital through a variety of means, including through public or private equity, debt financings or other sources, including up-front payments and milestone payments from strategic collaborations. To the extent that we raise additional capital through the sale of equity or convertible debt or equity securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Such financing may result in dilution to stockholders, imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to OP-1250 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.

Effective December 31, 2021, we are no longer an "emerging growth company," and the reduced reporting requirements applicable to "emerging growth companies" no longer apply, which increases our costs as a result of being a public company and places additional demands on management.

Effective December 31, 2021, we are no longer classified as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act, or the JOBS Act. As such, we will incur significant additional expenses that we did not previously incur in complying with the Sarbanes-Oxley Act and rules implemented by the SEC. If we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Furthermore, investor perceptions of our company may suffer if, in the future, material weaknesses are found, and this could cause a decline in the market price of our stock. Any failure of our internal control over financial reporting could have a material effect on our stated operating results. If we are unable to implement these changes effectively or efficiently, it could harm our operations, financial reporting or financial results and could result in an adverse opinion on internal control from our independent registered public accounting firm.

In addition, we have previously taken advantage of the JOBS Act's reduced disclosure requirements applicable to "emerging growth companies" regarding executive compensation and exemptions from the requirements of holding advisory say-on-pay votes on executive compensation. Since we are no longer classified as an "emerging growth company," we are no longer eligible for such reduced disclosure requirements and exemptions, though we will be eligible to take advantage of some reduced disclosure requirements applicable to "smaller reporting companies". As a result, we expect that because we are no longer classified as an "emerging growth company", we will require additional attention from management with respect to our disclosures and will incur increased costs, which could include higher legal fees, accounting fees, consultant fees and fees associated with investor relations activities, among others.

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

Because our annual revenue was less than $100.0 million during the most recently completed fiscal year and the market value of our voting and non-voting common stock held by non-affiliates was less than $560.0 million measured on the last business day of our second fiscal quarter for the year ending December 31, 2022, we qualify again as a "smaller reporting company" as defined in the Exchange Act. We may take advantage of certain of the scaled disclosures available to smaller reporting companies including, among other things, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act

("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.

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 Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Stock Market LLC and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will continue to increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control and procedures on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could significantly harm our business, financial condition, results of operations and prospects. We may also need to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

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

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

In addition, as a result of our disclosure obligations as a public company, our business and financial condition has become more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management's resources and seriously harm our business, financial condition, results of operations and prospects.

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

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, 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. For example, during August 2020, in connection with the preparation of our financial statements as of and for the years ended December 31, 2019 and 2018, we identified material weaknesses in our control over financial reporting. While we have remediated these material weaknesses and have implemented processes and controls over financial reporting to address the historical internal control deficiencies, there remains risk that future deficiencies may arise. 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.

We may be subject to securities litigation, which is expensive and could divert management attention.

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 shareholder derivative actions. We may be the target of these types of litigation and claims in the future. These claims and litigation against us could result in substantial costs and divert our management's attention from other business concerns, 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. Any return to stockholders will therefore be limited to any appreciation in the value of our common stock, which is not certain.

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.

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 the board 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 the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- prohibit our stockholders from calling a special meeting of our stockholders;
- prohibit cumulative voting;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called “poison pill,” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least $66^{2/3}\%$ of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our amended and restated certificate of incorporations or amended and restated bylaws.

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

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

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

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

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

This exclusive-forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business, financial condition, results of operations and prospects.

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

Recent Sales of Unregistered Securities

None.

Use of Proceeds from our Initial Public Offering of Common Stock

In November 2020, our Registration Statement on Form S-1 (No. 333-249748) was declared effective by the SEC and we issued and sold an aggregate of 12,650,000 shares of common stock (inclusive of 1,650,000 shares of common stock pursuant to the underwriters' exercise of their option to purchase additional shares) at a public offering price of $19.00 per share for aggregate net cash proceeds of approximately $220.6 million, after deducting underwriting discounts, commissions and offering costs. No payments for such expenses were

made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

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

There has been no material change in the planned use of proceeds from the IPO from that described in the prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on November 19, 2020.

Repurchase of Shares of Company Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

In November 2021, we were alerted to falsified information circulating on social media relating to our planned poster presentation for the Phase 1 dose-escalation portion of the ongoing Phase 1/2 clinical trial of OP-1250 at the San Antonio Breast Cancer Symposium. The falsified poster image was not released or authorized by us. In December 2021, a Special Committee of our Board of Directors, with assistance of outside counsel, initiated an investigation into the circumstances regarding these matters. The Special Committee's outside counsel contacted the SEC to inform of the Special Committee's investigation.

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	3.2	11/23/2020
10.1*+	Drug Discovery Collaboration and License Agreement by and between the Registrant and Aurigene Discovery Technologies Limited, dated June 7, 2022.				
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*	XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL Document				
101.SCH*	XBRL Taxonomy Extension Schema Document				
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document				
104	Cover Page Interactive Data File – The cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document				

* Filed herewith.
\+ Portions of this Agreement have been redacted in compliance with Regulation S-K Item 601(b)(10).

SIGNATURES

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

Olema Pharmaceuticals, Inc.

Date: August 9, 2022

By: /s/ Sean Bohen, M.D., Ph.D.

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

Olema Pharmaceuticals, Inc.

Date: August 9, 2022

By: /s/ Shane Kovacs

Shane Kovacs
Chief Operating and Financial Officer
(*Principal Financial Officer and Principal Accounting Officer*)

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

DRUG DISCOVERY COLLABORATION AND LICENSE AGREEMENT

THIS DRUG DISCOVERY COLLABORATION AND LICENSE AGREEMENT (the "**Agreement**") is entered into as of June 7, 2022 (the "**Effective Date**"), by and between **OLEMA PHARMACEUTICALS, INC.**, a corporation organized under the laws of Delaware, having its principal place of business at 512 2nd St, 4th Floor, San Francisco, CA 94107 (hereinafter "**Olema**") and **AURIGENE DISCOVERY TECHNOLOGIES LIMITED.**, a corporation organized under the laws of India, having its principal place of business at 39-40, KIADB Industrial Area, Electronic City Phase II, Hosur Road, Bangalore-560100, India (hereinafter "**Aurigene**"). Olema and Aurigene are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

WHEREAS, Aurigene has certain proprietary technology and intellectual property related to small molecule inhibitors of the human protein [*] (the "**Collaboration Target**");

WHEREAS, Olema is a pharmaceutical company that is interested in developing small molecule products that [*] the Collaboration Target;

WHEREAS, the Parties desire to pursue a collaborative research program to discover, develop and/or identify small molecule compounds that [*] the Collaboration Target, all in accordance with a Research Plan (as defined below); and

WHEREAS, following completion of the collaborative research program, Aurigene will grant to Olema, and Olema will accept, an exclusive license under Aurigene Patent Rights and Aurigene Know-How and Aurigene's interest in Collaboration Patent Rights and Collaboration Know-How to Develop, Manufacture and Commercialize Aurigene Compounds, Collaboration Compounds, and Licensed Products in the Field in the Territory (with capitalized terms as defined below), all in accordance with the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing and the premises and conditions set forth herein, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

1.1 "**Accounting Standards**" means GAAP or IFRS, in either case consistently applied. Each Party shall promptly notify the other in the event that it changes the Accounting Standards pursuant to which it maintains its records, it being understood that each Party may only use internationally recognized accounting principles.

1.2 "**Affiliate**" means, with respect to a particular Party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") means

the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of fifty percent (50%) or more of the voting stock of such entity, by contract or otherwise. An entity will be deemed to be an Affiliate for so long as such Control exists. Notwithstanding the foregoing, for the purposes of this Agreement, [*] shall not be considered an Affiliate of Aurigene except to the extent explicitly included herein.

1.3 "**Applicable Law**" means all applicable statutes, ordinances, regulations, rules, or orders of any kind whatsoever of any Governmental Authority, including the U.S. Food, Drug and Cosmetic Act, (21 U.S.C. §301 et seq.) ("**FFDCA**"), Prescription Drug Marketing Act, the Generic Drug Enforcement Act of 1992 (21 U.S.C. §335a et seq.), U.S. Patent Act (35 U.S.C. §1 et seq.), Federal False Claims Act (31 U.S.C. §3729 et seq.) ("**FCA**"), the Anti-Kickback Statute (42 U.S.C. §1320a-7b et seq.) ("**AKA**"), the U.S. Foreign Corrupt Practices Act of 1977 (15 U.S.C. §§78dd-1, et seq.) (the "**FCPA**"), and the United Kingdom Bribery Act (the "**UKBA**"), all as amended from time to time, together with any rules, regulations, and compliance guidance promulgated thereunder as well as foreign equivalents of any of the foregoing.

1.4 "**Aurigene Compound**" means any small molecule compound [*] and is owned or controlled by Aurigene as of the Effective Date and during the Term, but excluding any Excluded Compound and Collaboration Compound.

1.5 "**Aurigene Know-How**" means all Know-How Controlled by Aurigene, as of the Effective Date or during the Term, that is necessary or reasonably useful to Exploit Licensed Products in the Field in the Territory, excluding Aurigene's interest in any Collaboration Know-How; [*].

1.6 "**Aurigene Patents**" means all Patents Controlled by Aurigene, as of the Effective Date or during the Term, that: (i) Cover the composition of matter, the method of making or using, the sale or Exploitation of the Aurigene Compounds or a Licensed Product containing an Aurigene Compound, (ii) Cover the Aurigene Know-How, or (iii) are otherwise necessary or reasonably useful to Exploit the Licensed Products in the Field in the Territory, excluding Aurigene's interest in any Collaboration Patents. The Aurigene Patents as of the Effective Date include those set forth on Exhibit A; [*].

1.7 "**Business Day**" means a day other than Saturday, Sunday or any other day on which commercial banks located in San Francisco, California, or Bangalore, India are authorized or obligated by Applicable Law to close.

1.8 "**Calendar Quarter**" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31 of any Calendar Year; provided, however, that (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first complete Calendar Quarter thereafter; and (b) the last Calendar Quarter of the Term shall end upon the expiration or termination of this Agreement.

1.9 "**Calendar Year**" means the twelve-month period commencing on January 1 and ending on December 31; provided, however, that (a) the first Calendar Year of the Term shall begin on the Effective Date and end on December 31, 2022; and (b) the last Calendar Year of the Term shall end on the effective date of expiration or termination of this Agreement.

1.10 "**Centralized Approval Procedure**" means, to the extent compulsory for the Regulatory Approval of Products, the procedure administrated by the EMA which results in a single marketing authorization that is valid in all European Union countries, as well as in Iceland, Liechtenstein and Norway (as the list of such countries may change from time to time during the Term as set forth in the Applicable Laws).

1.11 "**Change of Control**" shall occur if: (a) any Third Party or group of Third Parties acting in concert, in one transaction or a series of related transactions, acquires directly or indirectly the beneficial ownership of any voting security of a Party, or if the percentage ownership of such person or entity in the voting securities of a Party is increased through stock redemption, cancellation or other recapitalization, and immediately after such acquisition or increase such Third Party or group of Third Parties acting in concert is, directly or indirectly, the beneficial owner of voting securities representing more than fifty percent (50%) of the total voting power of all of the then outstanding voting securities of a Party; (b) a merger, consolidation, recapitalization, or reorganization of a Party is consummated, other than any such transaction, which would result in stockholders or equity holders of such Party immediately prior to such transaction, owning at least fifty percent (50%) of the outstanding securities of the surviving entity (or its parent entity) immediately following such transaction; (c) the stockholders or equity holders of a Party approve a plan of complete liquidation of such Party, or an agreement for the sale or disposition by such Party of all or substantially of such Party's assets, other than pursuant to the transaction described above or to an Affiliate; or (d) the sale, transfer or disposition in one transaction or a series of related transactions to a Third Party or group of Third Parties acting in concert of (i) all or substantially all of such Party's assets taken as a whole or (ii) a majority of such Party's assets which relate to this Agreement, is effected.

1.12 "**Clinical Trials**" means a Phase I Trial, Phase II Trial, Phase III Trial or Phase IV Trial, as applicable.

1.13 **"Collaboration Compound**" means any small molecule compound that [*] the Collaboration Target and that is conceived and reduced to practice, during the Research Term, by a Party alone or jointly by the Parties pursuant to the Research Program.

1.14 "**Combination Product**" means (a) a product that comprises, consists of or incorporates a Licensed Product and at least one (1) other active pharmaceutical ingredient; (b) any Licensed Product sold in combination with one or more other products or services that are not Licensed Product for a single invoice price; or (c) any Licensed Product sold where the sale of the Licensed Product is only available from the seller with the purchase of other products or services that are not a Licensed Product.

1.15 "**Commercialization**" means any and all any activities directed to the offering for sale of an Aurigene Compound, a Collaboration Compound, a Licensed Product or other compound, product or therapy including: (a) activities directed to storing, marketing, promoting, detailing distributing, importing, offering to sell and/or selling the Aurigene Compound, Collaboration Compound, Licensed Product or other compound, product or therapy; (b) conducting Phase IV Trials of the Aurigene Compound, Collaboration Compound, Licensed Product, or other compound, product or therapy; (c) interacting with Regulatory Authorities regarding the foregoing; and (d) seeking Pricing Approvals (as applicable) for the Aurigene Compound, Collaboration Compound, Licensed Product or other compound, product or therapy in the Field in the Territory. When used as a verb, "**Commercialize**" means to engage in Commercialization activities.

1.16 "**Commercially Reasonable Efforts**" means, [*].

1.17 "**Competing Product**" means [*].

1.18 "**Competitive Infringement**" means (a) any existing, alleged or threatened infringement of an applicable Patent in the Field in the Territory resulting from (i) the using, making, importing, exporting, offering for sale or selling Licensed Products, Aurigene Compounds or Collaboration Compounds, or (ii) the filing of an ANDA under Section 505(j) of the FD&C Act or an application under Section 505(b)(2) of the FD&C Act naming a Licensed Product as a reference listed drug and including a certification under Section 505(j)(2)(A)(vii)(IV) or 505(b)(2)(A)(IV), respectively, or (b) a declaratory judgment action in connection with any infringement described in clause (a) or otherwise against any Patent seeking an order that any claim in such Patent is invalid or unenforceable.

1.19 "**Compound Patent**" means any claim contained in an Aurigene Patent or Collaboration Patent that claims the composition of matter of an Aurigene Compound or a Collaboration Compound [*].

1.20 "**Confidential Information**" means all non-public or proprietary Information disclosed by or on behalf of a Party to the other Party or its Affiliates or designee under this Agreement without regard as to whether any of the foregoing is marked "confidential" or "proprietary," or disclosed in oral, written, graphic, or electronic form. Confidential Information shall include: (a) with respect to each Party: (i) Confidential Information disclosed by or on behalf of such Party pursuant to the Confidential Disclosure Agreement and (ii) all Information or materials regarding or concerning any Compound, Product, or any other Know-How, technical or business information, that is communicated by or on behalf of one Party to the other Party or any of its Affiliates or designees; and (b) [*].

1.21 "**Control**" or "**Controlled**" means, with respect to any Information, Know-How, Patent or other intellectual property right, possession by a Party, including its Affiliates, of the ability (whether by ownership, license, or otherwise, other than pursuant to this Agreement) to grant access, a license or a sublicense to such Information, Know-How, Patent or other intellectual property right without [*].

1.22 "**Cover**", "**Covering**" or "**Covered**" with respect to a particular subject matter at issue and a relevant Patent or individual claim in such Patent, as applicable, that the composition, making, having made, use, sale, offer for sale, or importation of such subject matter would, in the absence of a license or other right to use, infringe one or more issued claims in such Patent, and for the purpose of determining such infringement of pending patent applications would infringe such pending claim if it were to issue.

1.23 "**Develop**" or "**Development**" means all activities relating to research and non-clinical and clinical drug development activities, including toxicology, carcinogenicity, pharmacology, and other non-clinical efforts, statistical analysis, formulation development, delivery system development, statistical analysis, manufacturing development, the performance of Clinical Trials or other activities reasonably necessary in order to obtain, but not maintain, Regulatory Approval of Products in the Field in the Territory. When used as a verb, "Develop" means to engage in Development activities. For clarity, "**Development**" shall not include any Commercialization activities.

1.24 "**EMA**" means the European Medicines Agency or any successor agency or authority having substantially the same function.

1.25 "**Excluded Compound**" means [*].

1.26 "**Executive Officers**" means (a) with respect to Olema, the Chief Executive Officer (or his or her designee), and (b) with respect to Aurigene, the Chief Executive Officer (or his or her designee).

1.27 "**Exploit**" or "**Exploitation**" means to make, have made, distribute, import, export, distribute, use, have used, sell, have sold, or offer for sale, including to Develop, Commercialize, register, modify, enhance, improve, Manufacture, have Manufactured or otherwise dispose of.

1.28 "**FDA**" means the United States Food and Drug Administration and any successor agency(ies) or authority having substantially the same function.

1.29 "**Field**" means any and all uses.

1.30 "**First Commercial Sale**" means, on a country-by-country basis, the first sale of a Licensed Product under this Agreement by Olema, its Affiliates or their respective sublicensees to a Third Party in a country in the Territory in the Field where Regulatory Approval of such Licensed Product has been obtained (excluding Pricing Approvals not required for Commercialization and except as set forth in the following sentence), and where such sale results in a Net Sale. [*].

1.31 "**Force Majeure**" means any event beyond the reasonable control of the affected Party, including embargoes, war or acts of war, terrorism, insurrections, riots, or civil unrest, strikes, lockouts or other labor disturbances; fire, floods, earthquakes or other acts of nature; acts, omissions or delays in acting by any Governmental Authority[*]; and failure of plant or machinery [*].

1.32 "**FTE**" means [*] of work per full Calendar Year (or equivalent pro-rata portion thereof for a period less than 12 months) devoted to or in support of the Research Program or other activity, that is carried out by one or more qualified scientific or technical employees of Aurigene or its Affiliates. Overtime, and work on weekends, holidays and the like will not be counted with any multiplier (*e.g.*, time-and-a-half or double time) toward the number.

1.33 "**GAAP**" means generally accepted accounting principles in the United States.

1.34 "**Good Clinical Practices**", "**GCP**" or "**cGCP**" means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in the guideline adopted by the International Conference on Harmonization ("**ICH**"), titled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," (or any successor document) including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the EMA, PMDA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time.

1.35 "**Good Laboratory Practices**", "**GLP**", or "**cGLP**" means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in 21 C.F.R. Part 58 (or any successor statute or regulation), including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the EMA, PMDA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time, including applicable guidelines promulgated under the ICH.

1.36 "**Good Manufacturing Practices**", "**GMP**", or "**cGMP**" means the then-current good manufacturing practices and procedures promulgated or endorsed by the FDA for the manufacture and testing of pharmaceutical materials, including, as applicable: (a) the principles detailed in the US Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, 601, 610 and 820; (b) European Directive 2003/94/EC and Eudralex 4; (c) the principles detailed in the WHO TRS 986 Annex 2, TRS 961 Annex 6 and TRS 957 Annex 2; (d) the quality guideline promulgated by the ICH designated ICH Q7A, titled "Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients" and (e) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time.

1.37 "**Governmental Authority**" means any multi-national, national, federal, state, local, municipal or other government authority of any nature (including any governmental division, subdivision, department, instrumentality, agency, bureau, branch, office, commission, council, court or other tribunal).

1.38 "**IFRS**" means the International Financial Reporting Standards, as promulgated by the International Standards According Board.

1.39 "**IND**" means (a) an Investigational New Drug application as defined in the FFDCA, as amended, and applicable regulations promulgated hereunder by the FDA, (b) a clinical trial authorization application for a product filed with a Regulatory Authority in

any other regulatory jurisdiction outside the U.S., the filing of which (in the case of (a) or (b)) is necessary to commence or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction, or (c) documentation issued by a Regulatory Authority that permits the conduct of clinical testing of a product in humans in such jurisdiction.

1.40 "**Information**" means information, ideas, inventions, discoveries, compounds, compositions, formulations, formulas, practices, procedures, processes, methods, knowledge, know-how, trade secrets, technology, techniques, designs, drawings, correspondence, computer programs, documents, apparatus, results, strategies; Regulatory Documentation and submissions pertaining to, or made in association with, filings with any Governmental Authority or patent office; data, including pharmacological, toxicological, non-clinical and clinical data, analytical and quality control data, manufacturing data and descriptions, market data, financial data or descriptions; devices, assays, chemical formulations, specifications, material, product samples and other samples, physical, chemical and biological materials and compounds, and the like; whether in written, electronic, oral or other tangible or intangible form, now known or hereafter developed, whether or not patentable.

1.41 "**Inventions**" means any and all inventions, discoveries and developments, whether or not patentable, made, conceived or reduced to practice in the course of performance of this Agreement, whether made, conceived or reduced to practice solely by, or on behalf of, Olema, Aurigene, the Parties jointly, or any Affiliate(s) of the same.

1.42 "**Know-How**" means all Information and Inventions of each Party that are necessary or useful to Exploit Products in the Field in the Territory. [*].

1.43 "**Liability**", "**Liabilities**" means losses, damages, fees, costs and other liabilities incurred by a Party related to such Party's performance or conduct, or by virtue of being a "Party", under this Agreement.

1.44 "**Licensed Product**" means any Product that contains an Aurigene Compound or Collaboration Compound as an active ingredient (alone or in combination with another active ingredient).

1.45 "**MAA**" or "**Marketing Authorization Application**" means an application for Regulatory Approval (but, for clarity, excluding a Pricing Approval) in any particular jurisdiction other than the U.S.

1.46 "**Major European Country**" means [*].

1.47 "**Major Market Country**" means the [*].

1.48 "**Manufacture**", "**Manufacturing**" means all activities related to making, having made, producing, manufacturing, modifying, reproducing, validating, scaling up, processing, filling, finishing, assembling, packaging, labeling, quality control, quality assurance, testing and release, shipping and storing of a Product, or any ingredient thereof, placebo or comparator agent, as the case may be, including manufacturing of finished

Product for Development and Commercialization, labeling, packaging, in-process and finished Product testing, release of Product or any component or ingredient thereof, including quality assurance activities related to manufacturing and release of a Product, and ongoing stability tests and regulatory activities related to any of the foregoing.

1.49 "**NDA Acceptance**" means the written notification by the FDA that the NDA has met all the criteria for filing acceptance pursuant to 21 C.F.R. §314.101.

1.50 "**Net Sales**" means, with respect to any Licensed Product, the gross amounts invoiced by [*].

[*]. In any event, any amounts received or invoiced by [*] shall be accounted for only once. For purposes of determining Net Sales, a Licensed Product shall be deemed to be sold [*] in accordance with the Accounting Standards. [*] Net Sales will not be imputed to [*]. With respect to revenue of a Party or its Affiliate, Net Sales shall be calculated [*].

With respect to the Net Sales of any Combination Product: [*].

1.51 "**Non-Compound Patent Royalty Term**" means, on a Licensed Product-by-Licensed Product and a country-by-country basis, the time period beginning with the First Commercial Sale of a Licensed Product in such country and continuing until the later of (a) the expiration of the last Valid Claim of an Aurigene Patent or Collaboration Patent, other than a Compound Patent, Covering such Licensed Product in such country and (b) the [*] of the date of the First Commercial Sale in such country.

1.52 "**Olema Know-How**" means all Know-How Controlled by Olema, as of the Effective Date or during the Term that is necessary or reasonably useful to Exploit the Licensed Products in the Field in the Territory, excluding Olema's interest in any Collaboration Know-How.

1.53 "**Olema Patents**" means all Patents Controlled by Olema, as of the Effective Date or during the Term that are necessary or reasonably useful to Exploit the Licensed Products in the Field in the Territory, excluding Olema's interest in any Collaboration Patents. The Olema Patents as of the Effective Date include those set forth on Exhibit B.

1.54 "**Patent Royalty Term**" means, on a Licensed Product-by-Licensed Product and a country-by-country basis, the time period beginning with the First Commercial Sale of a Licensed Product in such country and continuing until the expiration of the last Valid Claim of a Compound Patent Covering such Licensed Product in such country.

1.55 "**Patents**" means all: (a) issued patents, including any utility or design patent; (b) patent applications, including provisionals, substitutions, divisionals, continuations, continuations in-part or renewals; (c) patents of addition, restorations, extensions, supplementary protection certificates, registration or confirmation patents, patents resulting from post-grant proceedings, re-issues and re-examinations; (d) other patents or patent applications claiming priority directly or indirectly to any such specified patent or patent application specified in (a) through (c); and (e) inventor's certificates.

1.56 "**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision, department or agency of a government.

1.57 "**Phase I Trial**" means a human clinical trial of a Product [*] as more fully described in US federal regulation 21 C.F.R. § 312.21(a) and its equivalents in other jurisdictions.

1.58 "**Phase II Trial**" means a human clinical trial of a Product [*] as more fully described in US federal regulation 21 C.F.R. § 312.21(b) and its equivalents in other jurisdictions.

1.59 "**Phase III Trial**" means a pivotal human clinical trial of a Product on a sufficient number of patients, which trial is designed to: [*] support Regulatory Approval for the Product, as more fully described in US federal regulation 21 C.F.R. § 312.21(c) and its equivalents in other jurisdictions. [*]

1.60 "**Phase IV Trial**" means a human clinical trial of a Product, [*] which trial (a) is not required to be completed prior to obtaining Regulatory Approval of an indication; and (b) either (i) is required by the Regulatory Authority as mandatory to be conducted on or after the Regulatory Approval of an indication, or (ii) [*].

1.61 "**PMDA**" means Japan's Pharmaceuticals and Medical Devices Agency and any successor agency(ies) or authority having substantially the same function.

1.62 "**Pricing Approval**" shall mean, with respect to a Licensed Product, in any regulatory jurisdiction where a Regulatory Authority or other Third Party authorizes reimbursement for, or approves or determines pricing for, pharmaceutical products, receipt (or, if required to make such authorization, approval or determination effective, publication) of reimbursement authorization or pricing approval or determination (as the case may be) for a pharmaceutical product in such regulatory jurisdiction.

1.63 "**Product**" means any pharmaceutical product, including all forms, presentations, strengths, doses and formulations (including any method of delivery).

1.64 "**Product Liabilities**" means all Liabilities incurred by a Party, its Affiliates or its sublicensees and resulting from or relating to the use of a Product in a human (including Clinical Trials and/or commercialization) in the Territory incurred after the Effective Date. [*].

1.65 "**Project Leader**" means the person appointed by each Party from within their respective organization to coordinate and facilitate the communication, interaction and cooperation of the Parties pursuant to this Agreement, such person having the appropriate background and technical skills in [*] to lead each Party's efforts to discover and Develop Aurigene Compounds and Collaboration Compounds.

1.66 "**Regulatory Approval**" means any and all approvals [*], licenses, registrations or authorizations of any national, regional, state or local Regulatory Authority, department, bureau, commission, council or other governmental entity, that are necessary for the commercialization of a Licensed Product under this Agreement in the Territory.

1.67 "**Regulatory Approval Application**" means a New Drug Approval Application ("**NDA**") (as defined in the FFDCA), or any corresponding application for Regulatory Approval in the Territory, including: (a) with respect to the European Union, an MAA filed with the EMA pursuant to the Centralized Approval Procedure or with the applicable Regulatory Authority of a country in Europe with respect to the decentralized procedure, mutual recognition or any national approval procedure; and (b) an MAA filed with the PMDA, including, in each case, all supplements, amendments, variations, extensions and renewals thereof.

1.68 "**Regulatory Authority**" means any applicable Governmental Authority involved in granting Regulatory Approval in a country or jurisdiction in the Territory, including in the U.S., the FDA and any other applicable Governmental Authority having jurisdiction over the Product; in the EU, the EMA or any competent Governmental Authority in the EU; in Japan, the PMDA; and any other applicable Governmental Authority having jurisdiction over a Product.

1.69 "**Regulatory Documentation**" means, with respect to Products, all: (a) Regulatory Materials, including all data contained therein and any material supporting documents created for, submitted to or received from an applicable governmental agency or Regulatory Authority relating to such Regulatory Materials; and (b) other documentation or Information Controlled by a Party which is necessary in order to Exploit the Product in the Field in the Territory [*].

1.70 "**Regulatory Materials**" means, with respect to Products, all documentation, correspondence, submissions and notifications submitted to or received from a Regulatory Authority that are necessary or reasonably useful in order to Exploit a Product in the Field in the Territory. [*].

1.71 "**Research Data Package**" means, with respect to a given Collaboration Compound, [*].

1.72 "**Research Plan**" means the written plan covering the performance of activities in furtherance of the Research Program, which shall include, at minimum: [*]. The Research Plan includes the Initial Research Plan and the Supplemental Research Plan. The Research Plan may be amended from time to time in accordance with Section 3.3.

1.73 "**Target**" shall mean [*].

1.74 "**Territory**" means worldwide.

1.75 "**Third Party**" means any Person other than (a) Olema, (b) Aurigene or (c) an Affiliate of either of Olema or Aurigene.

1.76 "**U.S.**" means the United States of America, including its territories and possessions.

1.77 "**Valid Claim**" means (a) a claim of an issued and unexpired Patent to the extent such claim has not been revoked, held invalid or unenforceable by a patent office, court or other governmental agency of competent jurisdiction in a final order, from which no further appeal can be or has been taken, and which claim has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise; or (b) a claim within a patent application has not been pending for more than [*] from the earliest filing date to which such claim or the applicable patent application is entitled to claim priority and which claim has not been revoked, cancelled, withdrawn, held invalid or abandoned.

Additional Definitions. Each of the following definitions is set forth in the Section of this Agreement indicated below:

Definition	**Section**
"**Agreement**"	Preamble
"**AKA**"	1.3
"**Anti-Corruption Laws**"	7.2(c)
"**Aurigene**"	Preamble
"**Aurigene Indemnitee**"	10.1
"**Aurigene Materials**"	3.6
"**Aurigene Research Activities**"	3.1
"**Bankruptcy Laws**"	9.6(b)
"**Breaching Party**"	9.3(a)
"**Challenged Patent**"	9.5
"**Claim**"	10.1
"**Collaboration Inventions**"	6.1(c)
"**Collaboration Know-How**"	6.1(c)
"**Collaboration Patent**"	6.1(c)
"**Collaboration Target**"	Preamble
"**Confidential Disclosure Agreement**"	8.7
"**Cure Period**"	9.3(a)
"**Disclosing Party**"	8.1
"**Effective Date**"	Preamble
"**Existing Patents**"	7.3(c)
"**FCA**"	1.3
"**FCPA**"	1.3
"**FFDCA**"	1.3

Definition	**Section**
"**ICH**"	1.34
"**Indemnifying Party**"	10.3(a)
"**Indemnitee**"	10.3(a)
"**Initial Research Plan**"	3.1
"**Initial Research Term**"	3.4
"**Joint Research Activities**"	3.1
"**JRC**"	2.1(a)
"**Losses**"	10.1
"**NDA**"	1.67
"**Olema**"	Preamble
"**Olema Indemnitee**"	10.2
"**Olema Research Activities**"	3.1
"**Party**" or "**Parties**"	Preamble
"**Patent Extension**" or "**Patent Extensions**"	6.4
"**Proposed Terms**"	11.3(d)
"**Receiving Party**"	8.1
"**Records**"	3.8
"**Research Activities**"	3.1
"**Research Budget**"	1.72
"**Research Program**"	3.1
"**Research Term**"	3.4
"**Research Term Extension**"	3.4
"**Response Memorandum**"	11.3(e)
"[*]"	9.7(c)
"[*]"	9.7(c)
"**Royalty Term**"	5.3(c)
"**Substitute Target**"	3.11
"**Substitute Target Expiration Date**"	3.11
"**Supplemental Research Plan**"	3.1
"**Support Memorandum**"	11.3(d)
"**Term**"	9.1
"**Terminating Party**"	9.3(a)
"**UKBA**"	1.3

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

ARTICLE 2
GOVERNANCE

2.1 Joint Research Committee.

(a) Formation and Purpose. The Parties shall establish and convene a joint research committee (the "**JRC**") within [*] after the Effective Date. The JRC shall consist of an equal number of representatives from each Party and operate by the procedures in accordance with this Section 2.1. The purpose of the JRC shall be to provide a forum for the coordination, communication and oversight of the Parties' activities in furtherance of the Research Program, including the resolution of disputes properly referred to the JRC under this Agreement. Following the end of the last Research Term, the JRC shall automatically dissolve and have no further oversight of the Development and Commercialization of the Licensed Product.

(b) JRC Responsibilities. The JRC's primary responsibilities shall be to: [*].

(c) JRC Decisions and Actions. If the JRC fails to reach unanimous agreement on a matter before it for decision within [*] from the date that the matter is first presented to the JRC in writing, such matter shall be referred to the Executive Officers for discussion and resolution within [*] from the date that the matter is first referred to the Executive Officers. If the Executive Officers are not able to resolve the matter within the [*] period, then [*].

(d) JRC Membership. Promptly after the Effective Date, each Party shall designate [*] such representatives for the JRC. The JRC may elect to vary the number of representatives from time to time, provided that unless otherwise agreed by the Parties in writing at the JRC, the JRC shall maintain an equal number of representatives from each Party but no more than [*] JRC representatives in total. Each representative designated by a Party shall be an employee of such Party and shall have the appropriate level of experience in the subject area of the JRC, and at least [*] representative shall have sufficient seniority within the applicable Party's organization to have the necessary decision-making authority in order for the JRC to fulfill its responsibilities. Either Party may designate substitutes for its JRC representatives if [*] of such Party's designated representatives is unable to be present at a meeting. From time to time each Party may replace its JRC representatives by written notice to the other Party specifying the prior representative(s) and their replacement(s). Each representative shall be bound by confidentiality and non-use obligations at least as restrictive as those set forth in this Agreement.

(e) JRC Chairperson. The JRC will have co-chairpersons, with one co-chairperson to be designated by each Party. The co-chairpersons shall be responsible for calling and convening meetings but shall have no special authority over the other members of the JRC and shall have no additional voting rights. The co-chairpersons (or their designees) shall: (i) prepare and circulate an agenda reasonably in advance of each upcoming meeting; and (ii) prepare and issue minutes of the JRC meeting within [*] thereafter. Such minutes shall not be finalized until each JRC representative reviews and approves such minutes, provided that any minutes shall be deemed

approved unless a JRC representative objects to the accuracy of such minutes within [*] after the circulation of the minutes. [*].

(f) Meetings.

(1) ***Timing and Frequency***. No later than [*] after the Effective Date, the JRC will hold a meeting to establish the JRC's operating procedures. The JRC shall meet at least [*]. Additional meetings of the JRC may be held with the consent of each Party (such consent not to be unreasonably withheld, delayed or conditioned), as required under this Agreement or to resolve any matter or dispute referred to the JRC in accordance with this Agreement. In the case of any matter or dispute referred to the JRC, such meeting shall be held within [*] following referral to the JRC, or as soon as reasonably possible thereafter.

(2) ***Meeting Procedures***. Meetings of the JRC shall be effective only if a majority of representatives of each Party are present or participating. The JRC may meet either (i) in person at either Party's facilities or at such locations as the Parties may otherwise agree; or (ii) by audio or video teleconference; provided that [*]. Each Party shall be responsible for all of its own expenses incurred in connection with the JRC meeting, including all travel and lodging.

(3) ***Non-Member Participation***. Additional non-members of the JRC having relevant experience may from time to time be invited to participate in a JRC meeting, provided that such participants shall have no voting rights or powers. [*].

2.2 Additional Subcommittees and Working Groups. The JRC may establish other subcommittees or working groups, as needed to further the purposes of this Agreement, including any responsibilities assigned to the JRC under this Agreement[*]. The purpose, scope and procedures of any such subcommittee or working group shall be mutually agreed in writing by the JRC. Actions to be taken by any subcommittee or working group shall be taken only following unanimous vote, with each Party having [*]. If any subcommittee or working group fails to reach unanimous agreement on a matter before it for decision for a period in excess of [*] from the date that the matter is first presented to such subcommittee or working group in writing, such matter shall be referred to the JRC for resolution pursuant to Section 2.1.

2.3 Authority. The Parties agree that it shall be conclusively presumed that, unless otherwise explicitly stated, each voting member of the JRC, or each subcommittee or working group established by the JRC, has the authority and approval of such member's respective senior management in casting his or her vote. The JRC, and each subcommittee or working group established by the JRC, shall each have only the powers assigned expressly to the JRC in this ARTICLE 2 and elsewhere in this Agreement, and shall not have any power to amend, modify or waive compliance with this Agreement.

2.4 Project Leaders. Promptly following the Effective Date, each Party shall designate in writing a Project Leader to serve as the primary point of contact for the Parties regarding all activities contemplated under this Agreement. Each Project Leader shall, among other things: [*]. The Project Leaders shall be allowed to attend meetings of the JRC, as well as any subcommittee or working group established by the JRC of which the Project Leader is not a member.

2.5 Decision-Making Restrictions. Notwithstanding anything to the contrary in this Agreement, to the extent that [*] has final decision-making authority with respect to any matter pursuant to Section 2.1(c), [*] shall not exercise such final decision-making authority to: [*].

ARTICLE 3
RESEARCH PROGRAM

3.1 Purpose. The Parties will conduct a research program consisting of research activities directed at identifying, discovering and characterizing Collaboration Compounds, all in accordance with the Research Plan (the "**Research Program**"). The scope and specific terms governing the Research Program shall be set forth in a Research Plan. As of the Effective Date, the Parties have agreed upon the initial Research Plan (the "**Initial Research Plan**") attached hereto as Exhibit C. The JRC will have ultimate responsibility over all Research Program activities performed under this Agreement, in accordance with the terms of this Agreement. The Research Plan shall allocate the performance of specific research activities to each of Olema (the "**Olema Research Activities**") and Aurigene (the "**Aurigene Research Activities**") and shall specify activities, if any, to be performed jointly by the Parties (the "**Joint Research Activities**"). Within [*] after the Effective Date, the Parties will provide a supplemental Research Plan (the "**Supplemental Research Plan**") to the JRC for review and approval. Each Research Plan and the accompanying Research Budget shall be reviewed and/or amended by the JRC [*] in accordance with Section 3.3. For purposes of this Agreement, "**Research Activities**" shall mean, collectively, the Olema Research Activities, Aurigene Research Activities and Joint Research Activities. The Parties' Project Leaders will govern the day-to-day performance of the Research Activities. [*].

3.2 Research Licenses.

(a) License to Aurigene. Subject to the terms and conditions of this Agreement, Olema hereby grants to Aurigene a non-exclusive, royalty-free, non-transferable, non-sublicensable license, under the Olema Patents and Olema Know-How, solely to the extent necessary or reasonably useful for Aurigene to perform the Aurigene Research Activities and any Joint Research Activities during the Research Term.

(b) License to Olema. Subject to the terms and conditions of this Agreement, Aurigene hereby grants to Olema an exclusive, sublicensable license, under the Aurigene Patent Rights and Aurigene Know-How and Aurigene's interest in Collaboration Patent Rights and Collaboration Know-How, to make, use and import Aurigene Compounds, Collaboration Compounds, and Licensed Products in the Field in the Territory during the Research Term.

(c) No Implied Licenses. No license or other right is or shall be created or granted hereunder during the Research Program by implication, estoppel, or otherwise. All licenses and rights during the Research Program are or shall be granted only as expressly provided in this Section 3.2. All rights not expressly granted by a Party under this Agreement are reserved by such Party and may not be used by the other Party for any purpose.

(d) Expiration of Research Licenses. The licenses granted to each Party during the Research Program shall automatically terminate at the end of the Research Term.

3.3 Performance Standards; Research Plan. Each Party shall perform the Research Program activities for which it is responsible pursuant to the Research Plan and the terms and conditions of this Agreement, and in compliance with all Applicable Law, including, if and as applicable, national and international (e.g., ICH, GCP, GLP and GMP) guidelines. [*]. The Research Plan (including the Research Budget) shall be reviewed and amended by the Parties, through the JRC, [*]. Each updated Research Budget shall include, among other things, [*]. Each Party shall use Commercially Reasonable Efforts to complete the Research Program activities for which it is responsible in accordance with the timelines set forth in the Research Plan, and each Party will promptly inform the other Party if such Party anticipates or experiences a delay in the conduct or completion of any such activities.

3.4 Research Term. The Research Program shall commence on the Effective Date and expire [*] (the "**Initial Research Term**"), unless earlier terminated in accordance with ARTICLE 9. The Initial Research Term may be extended by mutual agreement of the Parties for additional [*], upon written notice to Aurigene (each, a "**Research Term Extension**", and together with the Initial Research Term, the "**Research Term**").

3.5 Research Costs. Olema will pay Aurigene for its work actually performed under the Research Plan according to, and not to exceed, the Research Budget at an FTE rate of [*]. Aurigene shall issue [*] invoices for its work actually performed under the Research Plan, which shall be due within [*] from Olema's receipt of each such invoice. Unless otherwise agreed in the Research Plan, including Olema's obligation to pay Aurigene according to the Research Budget, each Party shall be responsible for its own costs and expenses under a Research Plan. Notwithstanding the foregoing, Olema shall reimburse Aurigene for [*], to be paid by Olema within [*] following receipt of a detailed invoice from Aurigene identifying [*]. Upon request from Olema, Aurigene shall provide supporting documentation for the costs and expenses identified in such invoice.

3.6 Materials Transfer. In order to facilitate the activities contemplated under the Research Program, (a) Aurigene will promptly transfer to Olema, and no later than [*] after the Effective Date, the Aurigene Compounds and other technology and materials set forth in Exhibit D and (b) Aurigene will promptly transfer to Olema such other technology and materials within Aurigene Know-How as reasonably requested by Olema during the Term (collectively (a) and (b), the "**Aurigene Materials**"); [*]. Except as otherwise provided for under this Agreement, all such

Aurigene Materials delivered to Olema will remain the sole property of Aurigene, will be used by Olema only in furtherance of the Olema Research Activities or the Joint Research Activities or in performing any of its obligations or exercising any of its rights under this Agreement, without the prior written consent of Aurigene, and will be used in compliance with Applicable Law. Aurigene will provide Olema the most current material safety data sheet for the Materials upon transfer of any Materials. Except as expressly set forth in this Agreement and without limiting any of the representations and warranties expressly set forth in ARTICLE 7, THE AURIGENE COMPOUNDS AND AURIGENE MATERIALS ARE PROVIDED "AS IS" AND WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED.

3.7 Information Sharing and Reporting. Promptly after the Effective Date, the Parties will establish administrative procedures to achieve [*] electronic and data information sharing and reporting required under this Section 3.7. During the Research Term, each Party (through its respective Project Leader) will discuss progress and results in the conduct of Research Program activities for which it is responsible [*]. In addition, during the Research Term, each Party shall provide to the other Party at each regularly scheduled JRC meeting, a written report summarizing the Research Activities performed by such Party since the last JRC meeting and the results thereof and comparing such activities with such Party's obligations under the Research Plan for such time period. Each such report shall include [*]. [*].

3.8 Records. Each Party shall prepare and maintain, or shall cause to be prepared and maintained, complete and accurate written records, accounts, notes, reports and data (collectively, "**Records**") with respect to the Research Program activities conducted by such Party pursuant to this Agreement (including the Research Plan) in conformity with Applicable Law [*], provided that in no case shall such records be maintained for [*] to which such records pertain (or any longer period required by Applicable Law. If any such Records contain any Information that constitutes patentable subject matter for which either Party files a Patent, the filing Party shall notify the keeper of such Record in writing and such Record shall be maintained by the generating Party until [*].

3.9 Cooperation. Upon mutually acceptable advance notice, at the request of the JRC, each Party agrees to make its employees and consultants reasonably available at their respective places of employment to consult with the other Party on issues arising in connection with the Research Program.

3.10 Subcontracting. Each Party shall have the right to engage Affiliates or Third Party subcontractors to perform certain of its obligations under this Agreement; provided that, if Aurigene wishes to subcontract any of the Aurigene Research Activities under a Research Plan, then Aurigene must [*]. [*]. Notwithstanding the preceding, any Party engaging an Affiliate or subcontractor hereunder shall remain principally responsible and obligated for the performance of such activities. [*].

3.11 Substitute Target. At any time prior to [*] ("**Substitute Target Expiration Date**"), Olema shall have the right to substitute a Target for the Collaboration Target (a "**Substitute Target**"), subject to approval by Aurigene. If Olema elects to substitute a Target for the Collaboration Target, then Olema shall notify Aurigene in writing of its choice of Substitute Target prior to the Substitute Target Expiration Date, and, upon approval by Aurigene, such Substitute Target shall automatically become a Collaboration Target. Thereafter, the Parties will prepare and submit a new Research Plan for the Substitute Target for approval by the JRC.

ARTICLE 4
DEVELOPMENT AND COMMERCIALIZATION

4.1 General. Subject to the terms of this Agreement, at all times after expiration of the Research Term, Olema shall be solely responsible for and have sole authority with respect to, at its own expense, all Development, Manufacture, Regulatory Approval and Commercialization of the Collaboration Compounds, Aurigene Compounds and Licensed Products in the Field in the Territory and will retain final decision-making authority with respect thereto.

4.2 Commercial License; Sublicenses. Immediately upon expiration of the Research Term and for the remainder of the Term, subject to the terms and conditions of this Agreement, Aurigene hereby grants to Olema, effective on the expiration date of the Research Term, an exclusive, sublicensable (including through multiple tiers) license under Aurigene Patent Rights and Aurigene Know-How and Aurigene's interest in the Collaboration Compounds, Collaboration Patents and Collaboration Know-How, to research, Develop, Manufacture, Commercialize, export, import and otherwise Exploit Aurigene Compounds, Collaboration Compounds, and Licensed Products in the Field in the Territory. Any sublicenses granted by Olema or its Affiliates shall be in writing and subject to and consistent with the terms and conditions of this Agreement. Olema shall remain primarily responsible for the actions or omissions of its sublicensees or its sublicensees' sublicensees and their compliance with the terms of this Agreement. [*]. Within [*] after execution of a sublicense, Olema shall provide Aurigene with a reasonably redacted copy of each agreement granting a sublicense, but such copy shall not be redacted to the extent it impairs Aurigene's ability to ensure compliance with this Agreement. Olema shall notify Aurigene in writing within [*] after becoming aware of any effective termination of any sublicense agreement.

4.3 No Implied Licenses. Except as explicitly set forth in this Agreement, neither Party shall be deemed by estoppel or implication to have granted the other Party any license or other right to any intellectual property of such Party. [*].

4.4 Technology Transfer after Research Term. Within [*] after expiration of the Research Term, Aurigene, to the extent not previously transferred to Olema, shall provide Olema with copies of a Research Data Package [*] and all Aurigene Know-How and Aurigene Materials in Aurigene's possession and Control necessary or reasonably useful for the Exploitation of Aurigene Compounds, Collaboration Compounds, and Licensed Products in the Field in the Territory. The

Parties shall cooperate in the conduct of such technology transfer to ensure orderly transition and uninterrupted Development of the Aurigene Compounds and Collaboration Compounds. In addition, Aurigene shall make available to Olema, on a reasonable consultation basis, advice of its technical personnel as may reasonably be requested by Olema in connection with such transfer of Aurigene Know-How. [*].

4.5 Transition of Responsibilities After Expiration of the Research Term. Promptly after expiration of the Research Term, Aurigene shall, in accordance with the transition plan to be reasonably agreed by the Parties, transfer to Olema all activities and responsibilities related to the Collaboration Compounds, Aurigene Compounds and Licensed Products.

4.6 Mutual Exclusivity Obligations. During the Term, neither Party nor its Affiliates shall, license or otherwise permit any Third Party to, Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized or otherwise Exploit or have Exploited any Competing Product [*]. Notwithstanding the foregoing, (a) in the event of a Change of Control of Aurigene, [*], and (b) the requirements of this Section 4.6 shall cease to apply to Olema [*].

4.7 Development. Following expiration of the Research Term, Olema shall use Commercially Reasonable Efforts to [*]. Olema shall conduct all such activities in a good scientific manner and in compliance in all material respects with all Applicable Law, including applicable national and international (e.g., ICH, GCP, GLP, and GMP) guidelines.

4.8 Regulatory Matters.

(a) Preparation of Regulatory Materials. After expiration of the Research Term, Olema shall, with respect to Licensed Products in the Field in the Territory, have the sole right, at its own expense, to: [*].

(b) Aurigene Assistance. Aurigene shall assist Olema as reasonably requested [*] in connection with the preparation and filing of Regulatory Documentation for the Licensed Product in the Territory.

4.9 Commercialization.

(a) Commercialization Activities. Olema shall be solely responsible, at its own expense, for all aspects of the Commercialization of Licensed Products in the Field in the Territory. Olema shall use Commercially Reasonable Efforts to [*].

(b) Trademarks. Olema shall own and have sole responsibility, at its own expense, for all matters relating to the use of, and shall own, all trademarks used in the sale of Licensed Products in the Field in the Territory[*].

4.10 Manufacturing. Except as otherwise provided herein, after expiration of the Research Term, Olema shall have sole responsibility, at its own expense, for Manufacturing the Licensed Products for use in the Field in the Territory.

4.11 Progress Reports. During the Term, Olema shall, [*] provide to Aurigene a report detailing Olema's material efforts and progress with respect to the Development and Commercialization of Licensed Products during [*]. Each such report shall describe, among other matters, those: [*]. [*].

ARTICLE 5
COMPENSATION

5.1 Upfront Payment. Olema shall pay to Aurigene Eight Million United States Dollars ($8,000,000) as a one-time, non-refundable, non-creditable upfront payment within [*] after the Effective Date.

5.2 Development and Commercial Milestone Payments. Olema will promptly notify Aurigene in writing following the achievement of each milestone event described in subsections (a)-(c) below. Thereafter, Aurigene shall submit to Olema an invoice for the corresponding non-refundable, non-creditable milestone payment set forth below and Olema shall pay Aurigene such milestone payment within [*] after receipt of such invoice. [*].

(a) Development and Regulatory Milestones. The milestone events set forth in this Section 5.2(a) shall be payable only for the first Licensed Product to achieve such milestone, regardless of how many Licensed Products achieve such milestone.

No.	Milestone	Payment (U.S. Dollars)
1	[*]	[*]
2	[*]	[*]
3	[*]	[*]
4	[*]	[*]
	Maximum Development and Regulatory Milestone Payments	**$60,000,000**

[*].

(b) Commercial Milestones. The milestone payments set forth in this Section 5.2(b) shall each be payable only for the first Licensed Product to achieve such milestone, regardless of how many Licensed Products achieve such milestone.

No.	Milestone	Payment (U.S. Dollars)
1	[*]	[*]
2	[*]	[*]
3	[*]	[*]
	[*]	**[*]**

[*].

(c) Net Sales Milestones. The milestone payments in this Section 5.2(c) shall be payable only once, regardless of the number of times such milestone is achieved.

No.	Milestone	Payment (U.S. Dollars)
1	[*]	[*]
2	[*]	[*]
3	[*]	[*]
4	[*]	[*]
	[*]	**[*]**

[*].

5.3 Olema Royalty Obligations.

(a) Royalties for Licensed Products Covered by a Valid Claim of a Compound Patent. Olema shall pay to Aurigene royalties at the royalty rates on the [*] Net Sales of Licensed Products Covered by a Valid Claim of a Compound Patent in accordance with the tables below, in each case, during an applicable Patent Royalty Term and subject to Section 5.3(b). For the avoidance of doubt, (i) on a country-by-country basis, as to Net Sales of a Licensed Product made at a time when such Licensed Product is not Covered by a Valid Claim of a Compound Patent, royalties shall be payable in accordance with Section 5.3(b)[*].

[*] Net Sales	Royalty Rate
[*]	[*]
[*]	[*]

[*]	[*]

(b) Royalties for Licensed Products Not Covered by a Valid Claim of a Compound Patent. Olema shall pay to Aurigene royalties at the royalty rates on the [*] Net Sales of Licensed Products that are not Covered by a Valid Claim of a Compound Patent in accordance with the tables below, in each case, during an applicable Non-Compound Patent Royalty Term.

[*] Net Sales	Royalty Rate
[*]	[*]
[*]	[*]
[*]	[*]

(c) Royalty Term. Royalties under this Section 5.2(c) shall be payable beginning upon the First Commercial Sale of the Licensed Product in a country in the Territory until the expiration of the later of the Patent Royalty Term or Non-Compound Patent Royalty Term (collectively, the "**Royalty Term**") in such country. Following the expiration of the Royalty Term in a country of the Territory, subject to the terms and conditions of this Agreement, the license granted to Olema under Section 4.2 shall automatically become perpetual, irrevocable, non-exclusive, fully-paid and royalty-free in such country of the Territory.

5.4 Manner of Royalty Payment. Within [*] following the end of [*] after the First Commercial Sale of the Licensed Product in the Territory, Olema shall provide Aurigene with a report containing the following information for the applicable [*] on a Licensed Product-by-Licensed Product and country-by-country basis: [*]. Olema shall pay all amounts due to Aurigene pursuant to Section 5.2(c) with respect to Net Sales by [*] for such [*] within [*] after receipt of the corresponding invoice from Aurigene. [*].

5.5 Third Party Licenses. Olema shall have the right to offset [*].

5.6 Taxes.

(a) Cooperation and Coordination. The Parties acknowledge and agree that it is their mutual objective and intent to appropriately calculate, to the extent feasible and legal, taxes payable with respect to their collaborative efforts under this Agreement and that they shall use all reasonable efforts to cooperate and coordinate with each other to achieve such objective.

(b) Payment of Tax. [*].

(c) Assessment. Either Party may, at its own expense, protest any assessment, proposed assessment, or other claim by any Governmental Authority for any additional amount of taxes, interest or penalties or seek a refund of such amounts paid if permitted to do so by Applicable Law. The Parties shall reasonably cooperate with each other in any protest by providing records and such additional information as may reasonably be necessary for a Party to pursue such protest.

5.7 Audit. Each Party shall maintain complete and accurate records in sufficient detail to permit the other Party to confirm the accuracy of the calculation of Net Sales, royalties, and milestone payments under this Agreement, in the case of Olema, and costs and expenses of Research Activities, in the case of Aurigene. Upon reasonable prior notice, but not more than [*], such records shall be available during regular business hours at such place or places where such records are customarily kept, for a period of [*] to which they pertain for examination [*] at the expense of the requesting Party by an independent certified public accountant selected by the requesting Party and reasonably acceptable to the audited Party, for the sole purpose of verifying the accuracy of the financial reports and correctness of the payments furnished by the audited Party pursuant to this Agreement. All records made available for inspection or audit shall be deemed to be Confidential Information of the audited Party. The results of each inspection or audit, if any, shall be binding on both Parties. Any such auditor shall not disclose the audited Party's Confidential Information. The accounting firm will disclose to the auditing Party only whether the expenses and payments are correct or incorrect and the specific details concerning any discrepancies. No other information will be provided to the requesting Party without the prior consent of the audited Party unless disclosure is required by Applicable Laws or judicial order. The audited Party is entitled to require the accounting firm to execute a reasonable confidentiality agreement prior to commencing any such audit. The accounting firm shall provide a copy of its report and findings to the audited Party. Any amounts shown to be owed but unpaid shall be paid within [*] from the accountant's report[*] as set forth in Section 5.8 from the original due date. Any amounts shown to have been overpaid shall be refunded within [*] from the accountant's report. The requesting Party shall bear the full cost of such audit unless such audit discloses an underpayment by the other Party of [*], in which case the other Party shall bear the full cost of such audit. The audit rights set forth in this Section 5.7 shall survive the Term for a period of [*].

5.8 Late Payment. All payments due to a Party hereunder shall be made in U.S. Dollars by wire transfer of immediately available funds into an account designated by the receiving Party. If a Party does not receive payment of any sum due to it on or before the due date, [*].

ARTICLE 6
INTELLECTUAL PROPERTY MATTERS

6.1 Ownership of Inventions.

(a) Olema IP. As between the Parties, Olema shall own and Control all right, title and interest in and to (i) the Olema Patents and Olema Know-How, or (ii) all Patents or Know-How generated or acquired by Olema, whether solely or with, by or through its Affiliates or a Third

Party, outside the scope of the Research Program and this Agreement and without use of or reference to any Confidential Information of Aurigene.

(b) Aurigene IP. As between the Parties, Aurigene shall own and Control all right, title and interest in and to (i) the Aurigene Patents and Aurigene Know-How, or (ii) all Patents or Know-How generated or acquired by Aurigene, whether solely or with, by or through its Affiliates or a Third Party, outside the scope of the Research Program and this Agreement and without use of or reference to any Confidential Information of Olema.

(c) Collaboration Inventions. The Parties shall jointly own (i) the Collaboration Compounds and (ii) any Inventions made, conceived of or reduced to practice under the Research Program, together with any intellectual property rights therein (the "**Collaboration Inventions**"). Any Know-How within the Collaboration Inventions shall be "**Collaboration Know-How**" and any Patents filed with respect to such Collaboration Inventions shall be a "**Collaboration Patent**" (subject to the rights set forth in Section 6.3 regarding filing, prosecution, maintenance, enforcement and defense of Collaboration Patents). Inventorship shall be determined in accordance with U.S. patent laws. Each Party each hereby assigns and agrees to assign to the other Party an equal undivided interest in such Party's right, title and interest in and to any Collaboration Compound and any such Collaboration Invention. Subject to the rights, obligations and licenses granted under this Agreement, each Party shall have the right to use, and grant licenses to use, any Collaboration Inventions (including Collaboration Know-How and Collaboration Patents) without the other Party's consent and has no duty to account to the other Party for such use or license, and each Party hereby waives any right it may have under the laws of any country to require any such consent or accounting.

6.2 Disclosure of Inventions. Each Party shall promptly disclose to the other Party any Inventions made in the conduct of the Research Program. The disclosing Party will provide any invention disclosures, or other similar documents, submitted to it by its employees, agents or independent contractors describing such Inventions, and all Information relating to such Inventions to the extent necessary or useful for the Exploitation of Collaboration Compounds or Licensed Products containing Collaboration Compounds in the Field in the Territory and, to the extent patentable, for the preparation, filing and maintenance of any Patent with respect to such Invention.

6.3 Prosecution of Patents.

(a) Generally. As between the Parties, Olema shall have the first right, but not the obligation, to prepare, file, prosecute and maintain any Olema Patents, Aurigene Patents, and Collaboration Patents in the Territory, at Olema's sole cost and expense.

(b) Aurigene Patents and Collaboration Patents. Olema shall provide Aurigene with a reasonable opportunity to review and comment on all material correspondence and filings with respect to filing, prosecution and maintenance of the Aurigene Patents and the Collaboration Patents, including by providing Aurigene with a copy of material communications from any patent

authority in such country(ies) regarding any Aurigene Patents and the Collaboration Patents, and by providing drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses. Olema shall consider Aurigene's comments regarding such communications and drafts in good faith. If Olema determines in its discretion to abandon or not maintain any Aurigene Patent(s) or Collaboration Patent(s) in the Territory (without having first filed a continuation or substitute application), then Olema shall provide Aurigene with written notice of such determination within a period of time reasonably necessary to allow Aurigene to determine, in its discretion, whether to continue prosecution and maintenance of such Aurigene Patent(s) or Collaboration Patent(s). If Aurigene provides written notice expressing its interest in the preparation and filing, the continuation of prosecution or the maintenance of any such Aurigene Patent(s) or Collaboration Patent(s), Aurigene may prepare and file, continue prosecution of or maintain such Aurigene Patent(s) or Collaboration Patent(s) at its sole cost and expense; [*].

(c) Cooperation in Prosecution. Each Party shall provide the other Party all reasonable assistance and cooperation in the Patent prosecution efforts provided above in this Section 6.3, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution, as well as further actions as set forth below. Such assistance and cooperation shall include making a Party's inventors and other scientific advisors reasonably available to assist the other Party's Patent preparation, filing, prosecution and maintenance efforts. As used herein, "prosecution" of such Patents shall include all communication and other interaction with any patent office or patent authority having jurisdiction over a patent application in connection with pre-grant proceedings. [*].

6.4 Patent Term Extensions in the Territory. Olema, in its sole discretion, shall decide whether to seek patent term extensions, supplemental protection certificates or their equivalents in the Territory (each a "**Patent Extension**" and collectively "**Patent Extensions**") for Olema Patents, Aurigene Patents, and Collaboration Patents with respect to Licensed Products at its sole cost and expense. Aurigene will cooperate fully with Olema at Olema's expense in making such filings or actions, including executing any required authorizations to apply for such Patent Extension.

6.5 Orange Book Listing. Olema will have the full and exclusive right, in its sole discretion and in accordance with Applicable Law, to determine and control the listing of any Olema Patents, Aurigene Patents, and Collaboration Patents in the then-current edition of the FDA's Orange Book in connection with the Regulatory Approval of any Licensed Product, or in equivalent patent listings in any other country within the Territory. Aurigene will cooperate fully with Olema in such actions.

6.6 Infringement of Patents by Third Parties.

(a) Notification. Each Party shall promptly notify the other Party in writing of any Competitive Infringement of any Aurigene Patent or Collaboration Patent of which it becomes

aware and shall provide all Information in such Party's possession or control demonstrating such infringement.

(b) Infringement of Aurigene Patent or Collaboration Patent. Olema shall have the first right, but not the obligation, to bring an appropriate suit or other action against any Third Party engaged in any existing, alleged or threatened Competitive Infringement of any Aurigene Patent or Collaboration Patent. Olema shall notify Aurigene of its election to take any action against such Third Party within the earlier of: (i) [*] after the first notice under Section 6.6(a); or (ii) [*] before any time limit set forth in Applicable Law or regulation, including the time limits set forth under the Hatch-Waxman Act. In the event that Olema elects not to initiate a lawsuit or take other reasonable action with respect to an infringement described in this Section 6.6(b), Aurigene shall have the right, but not the obligation, to initiate such suit or take such other action, after providing [*] notice to Olema and giving good faith consideration to Olema's reason(s) for not initiating a suit or taking other action. [*] If one Party elects to bring suit or take action under this Section 6.6(b) against a Competitive Infringement, then the other Party shall have the right, prior to commencement of the suit or action, to join any such suit or action. Each Party shall provide to the Party enforcing any such rights under this Section 6.6(b) reasonable assistance in such enforcement, at such enforcing Party's request and expense, including joining such action as a party plaintiff if required by Applicable Law to pursue such action. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts, shall reasonably consider the other Party's comments on any such efforts, and shall consult the other Party in any important aspects of such enforcement, including determination of material litigation strategy and filing of dispositive papers to the competent court. Each Party shall bear all of its own internal costs incurred in connection with its activities under this Section 6.6(b), except as otherwise set forth above with respect to costs of providing cooperation. The Party not bringing an action with respect to the Competitive Infringement in the Territory under this Section 6.6(b) shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the Party bringing such action.

(c) Settlement. The enforcing Party shall not settle any claim, suit or action that it brought under this Section 6.6 involving Aurigene Patents or Collaboration Patents [*].

(d) Allocation of Proceeds. The Party bringing a claim, suit or action under Section 6.6(b) shall be solely responsible for any expenses incurred by such Party as a result of such claim, suit or action. If such Party recovers monetary damages in such claim, suit or action, such recovery shall be allocated first to the reimbursement of any expenses incurred by the Parties in such litigation, and any remaining amounts shall be allocated as follows: [*].

(e) Other Infringement. For any and all infringement of an Olema Patent, Olema shall have the sole right, but not the obligation, to bring an appropriate suit or other action against any person or entity engaged in such infringement of such Patent and to retain [*] of any recovery in connection with such suit or other action. Olema shall have no right to bring suit or other action

with respect to infringement of Aurigene Patents other than a Competitive Infringement. For an infringement by a Third Party of a Collaboration Patent other than a Competitive Infringement, the Parties will discuss in good faith the appropriate action to take against such infringement.

6.7 Infringement of Third Party Rights in the Territory.

(a) Notice. If any Licensed Product used or sold by Olema, its Affiliates, or sublicensees becomes the subject of a Third Party's claim or assertion of infringement of a Third Party Patent granted by a jurisdiction within the Territory, the Party first having notice of the claim or assertion shall promptly notify the other Party.

(b) Defense. Subject to any indemnification obligations of a Party to the other Party, Olema shall have the first right, but not the obligation, to defend any such Third Party claim or assertion of infringement, of a Third Party Patent as described in Section 6.7(a), at Olema's expense. If Olema does not commence actions to defend such claim within [*] after it receives notice thereof (or within [*] after it should have given notice thereof to Aurigene as required by Section 6.7(a)), then, to the extent allowed by Applicable Law, Aurigene shall have the right, but not the obligation, to control the defense of such claim by counsel of its choice, at Aurigene's expense. The non-defending Party shall reasonably cooperate with the Party conducting the defense of the claim or assertion, including if required to conduct such defense, furnishing a power of attorney; provided, however, that each Party shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense.

(c) Settlement. Neither Party shall enter into any settlement of any claim described in this Section 6.7 that [*].

6.8 Patent Oppositions and Other Proceedings.

(a) Third Party Patent Rights. Olema shall have the first right, but not the obligation, to determine whether to bring an opposition, action for declaratory judgment, nullity action, declaration for non-infringement, reexamination, inter partes review, post-grant proceeding or other attack upon the validity, title or enforceability of a Patent owned or controlled by a Third Party and having one or more claims that Cover the Licensed Product, or the use, sale, offer for sale or importation of the Licensed Product (except insofar as such action is a counterclaim to or defense of, or accompanies a defense of, a Third Party's claim or assertion of infringement under Section 6.7, in which case the provisions of Section 6.7 shall govern). Olema shall notify Aurigene prior to taking any such action. Aurigene shall be entitled to separate representation in such proceeding by counsel of its own choice and at its own expense and shall cooperate fully with Olema with respect to such action. Aurigene shall have a step-in right to bring any action not brought by Olema under this Section 6.8(a) in connection with any suit or other action that is controlled by Aurigene under Section 6.6(b).

(b) Parties' Patent Rights. If any Olema Patent, Aurigene Patent or Collaboration Patent becomes the subject of any proceeding commenced by a Third Party within the Territory in connection with an opposition, reexamination request, action for declaratory judgment, nullity action, interference, inter partes review or post-grant proceeding or other attack upon the validity, title or enforceability thereof (except insofar as such action is a counterclaim to or defense of, or accompanies a defense of, an action for infringement against a Third Party under Section 6.6, in which case the provisions of Section 6.6 shall govern), then Olema shall control such defense at its own expense. Olema shall permit Aurigene to participate in any proceeding involving an Aurigene Patent or Collaboration Patent to the extent permissible under Applicable Law, and to be represented by its own counsel in such proceeding, at Aurigene's expense. If Olema decides not to defend against such action involving an Aurigene Patent or Collaboration Patent, Aurigene shall have a backup right to assume the defense of such Third Party action at its own expense, but only after reasonably consulting with Olema and taking into account Olema's reasons for not pursuing such action. Any awards or amounts received in defending any such Third-Party action (solely with respect to any Aurigene Patent or Collaboration Patent) shall be allocated between the Parties as provided in Section 6.6(d).

ARTICLE 7
REPRESENTATIONS, WARRANTIES AND COVENANTS

7.1 Mutual Representations and Warranties. Each of the Parties hereby represents and warrants to the other Party as of the Effective Date that:

(a) Organization. It is a corporation duly organized, validly existing, and in good standing under Applicable Law of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement.

(b) Binding Agreement. This Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms, subject to the effects of bankruptcy, insolvency, or other Applicable Law of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity).

(c) Authorization. The execution, delivery, and performance of this Agreement by such Party have been duly authorized by all necessary corporate action and do not conflict with any agreement, instrument, or understanding, oral or written, to which it is a party or by which it is bound, nor violate any Applicable Law or any order, writ, judgment, injunction, decree, determination, or award of any court or governmental body, or administrative or other agency presently in effect applicable to such Party.

(d) No Inconsistent Obligations. Neither Party is under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms

of this Agreement, or that would impede the diligent and complete fulfillment of its obligations hereunder.

7.2 Mutual Covenants.

(a) No Debarment. Neither Party nor any of its respective Affiliates has been debarred by the FDA, is not subject to any similar sanction of other Governmental Authorities in the Territory, and, to its knowledge, neither Party nor any of its respective Affiliates has used, or will engage, in any capacity, in connection with this Agreement or any ancillary agreements (if any), any Person who either has been debarred by such a Regulatory Authority, or is the subject of a conviction described in Section 306 of the FFDCA. Each Party shall inform the other Party in writing promptly if it or any Person engaged by it or any of its Affiliates who is performing services under this Agreement or any ancillary agreements (if any) is debarred or is the subject of a conviction described in Section 306 of the FFDCA, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to such Party's knowledge, is threatened, relating to the debarment or conviction of such Party, any of its Affiliates or any such Person performing services hereunder or thereunder.

(b) Compliance. Each Party and its Affiliates shall comply in all material respects with all Applicable Law in the research, Development and Commercialization of Collaboration Compounds and Licensed Products and performance of its obligations under this Agreement, including, to the extent applicable to such Party and its activities hereunder, the statutes, regulations and written directives of the FDA, the EMA and any Regulatory Authority having jurisdiction in the Territory, the FD&C Act, the Prescription Drug Marketing Act, the Federal Health Care Programs Anti-Kickback Law, 42 U.S.C. 1320a-7b(b), the statutes, regulations and written directives of Medicare, Medicaid and all other health care programs, as defined in 42 U.S.C. § 1320a-7b(f), as each as may be amended from time to time.

(c) Anti-Corruption Laws. Each Party shall comply with the United States Foreign Corrupt Practices Act (FCPA), the UK Bribery Act 2010 or any other applicable equivalent laws (collectively "**Anti-Corruption Laws**") and shall not cause the other Party or its Affiliates, directors, officers, shareholders, employees or agents to be in violation of any Anti-Corruption Laws. Without limiting the foregoing, neither Party shall, directly or indirectly, pay any money to, or offer or give anything of value to, any "foreign official" as that term is used in the FCPA or any "foreign public official" as that term is used in the FCPA, in order to obtain or retain business or to secure any commercial or financial advantage for the other Party or for itself or any of their respective Affiliates or sublicensees. A breach of this Section 7.2(c) shall be deemed a material breach of this Agreement.

(d) Assignment by Employees, Agents and Consultants; Inventor Remuneration. During the Research Term, all employees, agents and subcontractors of, and consultants to, each Party or its Affiliates who are performing activities under the Research Plan will be obligated to assign to such Party or its Affiliate their rights in and to any Inventions arising out of their work

at such Party or its Affiliate either pursuant to written agreement or by operation of Applicable Law, except as set forth in Section 3.10 with respect to subcontractor background intellectual property and improvements thereto. During the Term, each Party will pay all such remuneration due to any inventor employed or previously employed by such Party or any of its Affiliates with respect to any Inventions, Information, and other Know-How and intellectual property rights therein that are assigned to such Party or its Affiliates.

7.3 Additional Representations and Warranties of Aurigene. Aurigene represents and warrants to Olema that, as of the Effective Date:

(a) Aurigene has all rights necessary to grant the licenses under the Aurigene Patents and Aurigene Know-How that it grants to Olema in this Agreement. Aurigene has not granted to any Third Party rights that encumber or conflict with the rights granted to Olema hereunder with respect to the Aurigene Patents and Aurigene Know-How.

(b) Aurigene has not received any notice or threat from any Third Party asserting or alleging, nor does Aurigene have any knowledge of any basis for any assertion or allegation, that any Development, Manufacture, Commercialization or Exploitation of Aurigene Compounds or Products containing Aurigene Compounds infringed or would infringe the intellectual property rights of such Third Party.

(c) The Patents set forth on Exhibit A ("**Existing Patents**") represent all Aurigene Patents as of the Effective Date. Aurigene is the sole and exclusive owner of or the exclusive licensee to the entire right, title and interest in the Existing Patents free of any encumbrance, lien, or claim of ownership by any Third Party. Aurigene or its Affiliates have not received any written notification of actual infringement or misappropriation of the Existing Patents or of any threatened claims or litigation seeking to invalidate or otherwise challenge the Existing Patents by any Person in the Territory, and there is no pending or, to Aurigene's knowledge, threatened, litigation with respect to infringement or misappropriation of the Aurigene Patents by any Person in the Territory. To Aurigene's knowledge, neither Aurigene nor any of its Affiliates have taken any action that would render any Invention claimed in the issued Existing Patents unpatentable.

(d) Aurigene or its Affiliates have not received any written notification of actual claims, disputes, proceedings, or allegations regarding or relating to improper inventorship of the Existing Patents.

7.4 Additional Covenant of Aurigene. During the Term, Aurigene shall not, and shall cause its Affiliates not to, grant to any Third Party rights that encumber or conflict with the rights granted to Olema hereunder with respect to the Aurigene Patents and Aurigene Know-How and Aurigene's interest in Collaboration Patent Rights and Collaboration Know-How.

7.5 No Other Representations or Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS ARTICLE 7, THE PARTIES MAKE NO REPRESENTATIONS OR WARRANTIES OF

ANY KIND WHATSOEVER, EITHER EXPRESS OR IMPLIED, WRITTEN OR ORAL, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, INCLUDING ANY EXPRESS OR IMPLIED WARRANTY OF QUALITY, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR WARRANTY OF NON-INFRINGEMENT OR AS TO THE VALIDITY OF ANY PATENTS.

ARTICLE 8
CONFIDENTIALITY

8.1 Nondisclosure. Each Party agrees that, during the Term and for a period of [*] thereafter, a Party (the "**Receiving Party**") receiving Confidential Information of the other Party (the "**Disclosing Party**") shall: (a) maintain in confidence such Confidential Information using not less than the efforts such Receiving Party uses to maintain in confidence its own confidential or proprietary Information of similar kind and value (but at a minimum each Party shall use Commercially Reasonable Efforts), (b) not disclose such Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted below, and (c) not use such Confidential Information for any purpose except those permitted by this Agreement (it being understood that this Section 8.1 shall not create or imply any rights or licenses not expressly granted under this Agreement).

8.2 Exceptions. The obligations in Section 8.1 shall not apply with respect to any portion of the Confidential Information to the extent that the Receiving Party can show by competent written evidence:

(a) is (at the time of disclosure) or becomes (after the time of disclosure) known to the public or part of the public domain through no breach of this Agreement by the Receiving Party;

(b) is known to, or was otherwise in the possession of, the Receiving Party or any of its Affiliates, without any obligation to keep it confidential or any restriction on its use, prior to disclosure by the Disclosing Party;

(c) is subsequently disclosed to the Receiving Party or any of its Affiliates on a non-confidential basis by a Third Party that is not bound by a similar duty of confidentiality or restriction on its use;

(d) is independently discovered or developed by or on behalf of the Receiving Party or any of its Affiliates, as evidenced by its written records, without the aid, application, use or reference to of Confidential Information disclosed by the Disclosing Party or its Affiliates under this Agreement; or

(e) is the subject of written permission to disclose provided by the Disclosing Party.

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

8.3 Authorized Disclosure. The Receiving Party may disclose Confidential Information (including this Agreement) of the Disclosing Party only to the extent such disclosure is reasonably necessary in the following instances:

(a) to a Governmental Authority or other Regulatory Authority in order to file or prosecute Patents as permitted by this Agreement;

(b) to a Governmental Authority or other Regulatory Authority as reasonably required in generating Regulatory Materials and obtaining Regulatory Approvals;

(c) prosecuting or defending litigation, including responding to a subpoena in a Third Party litigation;

(d) to the extent required in connection with complying with Applicable Law or court or administrative orders;

(e) if such disclosure is deemed necessary by the Receiving Party to be disclosed to such Party's attorneys, independent accountants or financial advisors for the sole purpose of enabling such attorneys, independent accountants or financial advisors to provide advice to the Receiving Party, on the condition that such attorneys, independent accountants and financial advisors are bound by confidentiality and non-use obligations substantially as protective as the confidentiality provisions of this Agreement as they apply to the Receiving Party; provided, however, that, the Receiving Party shall remain responsible for any failure by any Person who receives Confidential Information pursuant to this Section 8.3(e) to treat such Confidential Information as required under this ARTICLE 8;

(f) to existing or bona fide prospective acquirers, merger partners, lenders or investors of the Receiving Party in connection with transactions or bona fide prospective transactions with the foregoing, in each case on a "need-to-know" basis, under appropriate written confidentiality provisions substantially similar to those of this Agreement [*]; provided, however, that, the Receiving Party shall remain responsible for any failure by any Person who receives Confidential Information pursuant to this Section 8.3(f) to treat such Confidential Information as required under this ARTICLE 8; and

(g) to its Affiliates, and each of its and its Affiliates' employees, sublicensees or prospective sublicensees, subcontractors or prospective subcontractors, in each case, on a "need-to-know" basis in order for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement, to the extent reasonably necessary for such purposes; each of whom prior to disclosure must be bound by written obligations of confidentiality and restrictions on use of such Confidential Information that are substantially similar to those set forth in this ARTICLE 8; provided, however, that: (i) the Receiving Party shall remain responsible for any failure by any Person who receives Confidential Information pursuant to this Section 8.3(g) to treat such Confidential Information as required under this ARTICLE 8 and (ii) with respect to disclosures to

sublicensees or prospective sublicensees or subcontractors or prospective subcontractors, the financial terms of this Agreement shall be redacted from any such disclosure of the terms of this Agreement.

If and whenever any Confidential Information is disclosed in accordance with this Section 8.3, such disclosure shall not cause any such information to cease to be Confidential Information except to the extent that such disclosure results in a public disclosure of such information (other than by breach of this Agreement). Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to clauses (a) through (e) of this Section 8.3, it will, except where impracticable, give reasonable advance notice to the other Party of such disclosure and use not less than the same efforts to secure confidential treatment of such information as it would to protect its own confidential information from disclosure.

8.4 Terms of this Agreement. **[*]**

8.5 Breaches of Confidentiality; Assistance in Respect of Same. The Receiving Party shall promptly notify the Disclosing Party if the Receiving Party becomes aware of any breach of confidence or unauthorized use by any Person to whom the Receiving Party has disclosed any Confidential Information. The Receiving Party shall give the Disclosing Party all reasonable assistance in connection with any action, demand, claim or proceeding that the Disclosing Party may institute against any such person in respect of such disclosure.

8.6 Securities Filings. Notwithstanding anything to the contrary in this ARTICLE 8, in the event either Party determines it is reasonably advisable or otherwise required to file with the Securities and Exchange Commission or the securities regulators of any state or other jurisdiction a registration statement or any other disclosure document that describes or refers to the terms and conditions of this Agreement or any related agreements between the Parties, or requires the filing of this Agreement as an exhibit to such registration, statement or disclosure document, such Party shall notify the other Party of such intention and shall provide the other Party, except where impracticable, with a copy of relevant portions of the proposed filing at least [*] prior to such filing (and any revisions to such portions of the proposed filing [*] prior to the filing thereof), including any exhibits thereto that refer to the other Party or the terms and conditions of this Agreement or any related Agreements between the Parties. The Party making such filing shall cooperate in good faith with the other Party to obtain confidential treatment of the terms and conditions of this Agreement or any related Agreements between the Parties that the other Party reasonably requests be kept confidential or otherwise afforded confidential treatment and shall only disclose Confidential Information that it is reasonably advised by outside counsel is legally required to be disclosed. Each Party acknowledges that the other Party may be required by securities regulators, including the Securities and Exchange Commission, or advised by such other Party's outside counsel that the financial terms, including the milestone amounts and/or royalty rates must be included in such filings. No such notice shall be required if the description of or reference to this Agreement or a related agreement between the Parties contained in the proposed

filing has been included in any previous filing made by either Party in accordance with this Section 8.6 or otherwise approved by the other Party.

8.7 Relationship to Confidentiality Agreement. This Agreement supersedes that certain Mutual Confidential Disclosure Agreement between the Parties dated [*] (the "**Confidential Disclosure Agreement**"), provided however, that all "Confidential Information" disclosed or received by the Parties and their Affiliates thereunder shall be deemed Confidential Information hereunder and shall be subject to the terms and conditions of this Agreement.

8.8 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that could result to a Party upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this ARTICLE 8. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this ARTICLE 8.

8.9 Publicity.

(a) Press Release. Olema and Aurigene may each issue one press release announcing the execution of this Agreement on the Effective Date or immediately thereafter without any changes from the form attached to this Agreement as Exhibit E. Beyond such press release, neither Party shall make any public announcements concerning the material terms of this Agreement or any activities hereunder without the other Party's prior written consent. If a Party desires to subsequently make a public announcement concerning the material terms of this Agreement or any activities hereunder, such Party shall give reasonable prior advance notice of the proposed text of such announcement to the other Party for its prior review and approval (except as otherwise provided herein), except that in the case of a press release or governmental filing required by law, the disclosing Party shall provide the other Party with such advance notice as it reasonably can and shall not be required to obtain approval therefor. A Party commenting on such a proposed press release shall provide its comments, if any, within [*] after receiving the press release for review. Notwithstanding anything to the contrary herein, neither Party shall be required to seek the permission of the other Party to repeat any information that has already been publicly disclosed by such Party, or by the other Party, in accordance with this Section 8.9(a), provided such information remains accurate as of such time.

(b) Publications. During the Term, Olema may, in its sole discretion, publish all data and information generated from the Research Program and non-clinical and Clinical Trials conducted with respect to the Aurigene Compounds, Collaboration Compounds or Licensed Products, and Aurigene shall have no such right to publish [*]. Olema shall provide Aurigene with a copy of the applicable proposed abstract, manuscript, or presentation no less than [*] prior to its intended submission for publication. Aurigene shall respond in writing at least [*] prior to the intended publication date with any concerns regarding patentability or protection of Aurigene's Confidential Information. In the event of concern over patent protection of intellectual property

rights of Aurigene, Olema agrees not to submit such publication or to make such presentation that contains such information until Aurigene is given a reasonable period of time, and in no event less than [*], to seek patent protection in accordance with the terms of this Agreement for any material in such publication or presentation which it believes is patentable. Subject to Section 8.3, any Confidential Information of Aurigene shall, if requested by Aurigene, be removed by Olema.

(c) Publication Guidelines. All publications shall be prepared, presented and/or published in accordance with pharmaceutical industry accepted guidelines [*].

ARTICLE 9
TERM AND TERMINATION

9.1 Term. This Agreement shall become effective as of the Effective Date and, unless earlier terminated pursuant to this ARTICLE 9, shall continue in full force and effect until the date of expiration of all payment obligations under this Agreement (the "**Term**").

9.2 Unilateral Termination by Olema. Olema shall have the right to terminate this Agreement in its entirety, for any or no reason, upon [*] prior written notice to Aurigene.

9.3 Termination for Material Breach.

(a) Either Party (the "**Terminating Party**") may terminate this Agreement in its entirety or on a Licensed Product-by-Licensed Product basis in the event the other Party (the "**Breaching Party**") has materially breached this Agreement, and such material breach has not been cured within [*] after receipt of written notice of such breach by the Breaching Party from the Terminating Party or, if such breach is not reasonably curable within such [*] period but is curable, such longer period as reasonably necessary for the Breaching Party to cure such material breach (the "**Cure Period**")[*]. The written notice describing the alleged material breach shall provide sufficient detail to put the Breaching Party on notice of such material breach. Any termination of this Agreement pursuant to this Section 9.3 shall become effective at the end of the Cure Period unless the Breaching Party has cured any such material breach prior to the expiration of such Cure Period. The right of either Party to terminate this Agreement as provided in this Section 9.3 shall not be affected in any way by such Party's waiver of or failure to take action with respect to any previous breach under this Agreement.

(b) Any right to terminate this Agreement, in its entirety or with respect to a Licensed Product, under this Section 9.3 shall be stayed and the cure period tolled if, during any cure period, the Breaching Party initiates dispute resolution by the Executive Officers and/or an action or proceeding in accordance with Section 11.2 with respect to such breach.

9.4 Alternative to Olema Termination for Certain Aurigene Material Breach. [*]

9.5 Termination for Patent Challenge. If Olema, its Affiliates or any of their respective sublicensees, directly or indirectly disputes, or assists any Third Party to dispute the validity of any granted Patent within the Aurigene Patents or Collaboration Patents (such Patent, the "**Challenged Patent**") in a litigation or other court proceeding with respect to a Licensed Product, Aurigene may terminate the license in Section 3.2 or Section 4.2 with respect to such Challenged Patent upon [*] prior written notice to Olema, unless during such [*] period the subject challenge is permanently dismissed or withdrawn and is not thereafter reinstituted or continued. Notwithstanding the foregoing, in the event a sublicensee of Olema initiates such challenge, Aurigene may not terminate the license granted in Section 3.2 or Section 4.2 with respect to such Challenged Patent if: (a) Olema successfully causes such sublicensee to permanently cease such challenge as aforesaid within such [*] period; or (b) Olema (i) provides Aurigene a written notice of its intent to terminate its sublicense agreement with such sublicensee within [*] of receiving written notice from Aurigene, and (ii) successfully terminates such sublicense within such [*] period. [*]

9.6 Termination for Bankruptcy.

(a) Either Party may terminate this Agreement in its entirety upon providing written notice to the other Party on or after the time that such other Party makes a general assignment for the benefit of creditors, files an insolvency petition in bankruptcy, petitions for or acquiesces in the appointment of any receiver, trustee or similar officer to liquidate or conserve its business or any substantial part of its assets, commences under the laws of any jurisdiction any proceeding involving its insolvency, bankruptcy, reorganization, adjustment of debt, dissolution, liquidation or any other similar proceeding for the release of financially distressed debtors, or becomes a party to any proceeding or action of the type described above, and such proceeding or action remains un-dismissed or un-stayed for a period of more than [*].

(b) All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the U.S. Code and other similar laws in any jurisdiction outside the U.S. (collectively, the "**Bankruptcy Laws**"), licenses of rights to "intellectual property" as defined under the Bankruptcy Laws. If a case is commenced during the Term by or against a Party under Bankruptcy Laws then, unless and until this Agreement is rejected as provided pursuant to such Bankruptcy Laws, such Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a Title 11 trustee) shall perform all of the obligations in this Agreement intended to be performed by such Party. If a case is commenced during the Term by or against a Party under the Bankruptcy Laws, this Agreement is rejected as provided for under the Bankruptcy Laws, and the non-bankrupt Party elects to retain its rights hereunder as provided for under the Bankruptcy Laws, then the Party subject to such case under the Bankruptcy Laws (in any capacity, including debtor-in-possession) and its successors and assigns (including a Title 11 trustee), shall provide to the non-bankrupt Party copies of all Patents and Information necessary for the non-bankrupt Party to prosecute, maintain and enjoy its rights under the terms of this Agreement. All rights, powers and remedies of the non-bankrupt

Party as provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including the Bankruptcy Laws) in the event of the commencement of a case by or against a Party under the Bankruptcy Laws.

9.7 Effects of Termination. All of the following effects of termination are in addition to the other rights and remedies that may be available to either of the Parties under this Agreement and shall not be construed to limit any such rights or remedies. In the event this Agreement is not terminated in its entirety, but rather is terminated on a Licensed Product-by-Licensed Product basis pursuant to Section 9.3, then, notwithstanding anything to the contrary in this Section 9.7, the consequences of termination described herein shall only apply to such terminated Licensed Product, and this Agreement shall remain in full force and effect with respect to all Products other than such terminated Licensed Product.

(a) General. In the event of termination of this Agreement by either Party:

(1) The JRC shall coordinate the wind-down of each Party's efforts under this Agreement if termination occurs during the Research Term.

(2) Without limiting the effect that such termination shall have on any provisions of this Agreement, other than those provisions that this Agreement expressly provides shall survive such termination or as otherwise expressly provided herein, including Sections 9.7(b) and (c), all rights and licenses granted herein to either Party shall terminate; provided that such licenses shall continue as necessary for the Parties to complete the orderly wind-down of their activities under this Agreement in accordance with Applicable Law and as otherwise required in accordance with Section 9.7(a)(1) or Section 9.7(a)(5);

(3) [*];

(4) All payment obligations hereunder shall terminate, other than those that accrued prior to the effective date of termination; and

(5) [*].

(b) Consequences of Unilateral Termination by Olema. Upon termination of this Agreement in its entirety by Olema in accordance with Section 9.2 prior to the time Aurigene has in good faith sent a written notice to Olema claiming a material breach of this Agreement by Olema, which claim of breach has not yet been resolved: [*]

(c) Consequences for Aurigene Termination for Olema Material Breach or After Aurigene Notice of Material Breach. In connection with termination of this Agreement (i) by Aurigene in accordance with Section 9.3 or Section 9.5 with respect to one or more Collaboration Compounds or Aurigene Compounds [*] or Licensed Products that contain such Collaboration

Compound or Aurigene Compound as an active ingredient (alone or in combination with another active ingredient) [*] or (iii) in its entirety by Olema in accordance with Section 9.2 after the time Aurigene has in good faith sent a written notice to Olema claiming a material breach of this Agreement by Olema, which claim of breach has not yet been resolved. [*].

9.8 Remedies. Except as otherwise explicitly set forth in this Agreement, termination or expiration of this Agreement shall not relieve the Parties of any Liability or obligation which accrued hereunder prior to the effective date of such termination or expiration, nor prejudice either Party's right to obtain performance of any obligation.

9.9 Survival. In the event of termination of this Agreement, in addition to the provisions of this Agreement that continue in effect in accordance with their terms, the following provisions of this Agreement shall survive: ARTICLE 1, Section 3.8, Section 5.6, Section 5.7, Section 5.8, Section 6.1, Section 7.5, ARTICLE 8, Section 9.7, Section 9.8, Section 9.9, ARTICLE 10, and ARTICLE 11.

ARTICLE 10
INDEMNIFICATION

10.1 Indemnification by Olema. Olema hereby agrees to defend, indemnify and hold harmless Aurigene and its Affiliates, and each of their respective directors, officers, employees, agents and representatives (each, an "**Aurigene Indemnitee**") from and against any and all claims, suits, actions, demands, liabilities, expenses and/or losses, including reasonable legal expenses and attorneys' fees (collectively, the "**Losses**"), to which any Aurigene Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party (each, a "**Claim**") to the extent such Losses arise directly or indirectly out of: [*].

10.2 Indemnification by Aurigene. Aurigene hereby agrees to defend, indemnify and hold harmless Olema and its Affiliates and each of their respective directors, officers, employees, agents and representatives (each, an "**Olema Indemnitee**") from and against any and all Losses to which any Olema Indemnitee may become subject as a result of any Claim to the extent such Losses arise directly or indirectly out of: [*].

10.3 Indemnification Procedures.

(a) Notice. Promptly after a Olema Indemnitee or a Aurigene Indemnitee (each, an "**Indemnitee**") receives notice of a pending or threatened Claim, such Indemnitee shall give written notice of the Claim to the Party from whom the Indemnitee is entitled to receive indemnification pursuant to Sections 10.1 or 10.2, as applicable (the "**Indemnifying Party**"). However, an Indemnitee's delay in providing or failure to provide such notice shall not relieve the Indemnifying Party of its indemnification obligations, except to the extent it can demonstrate prejudice due to the delay or lack of notice.

(b) Defense. Upon receipt of notice under this Section 10.3 from the Indemnitee, the Indemnifying Party will have the duty to either compromise or defend, at its own expense and by counsel (reasonably satisfactory to Indemnitee) such Claim. The Indemnifying Party will promptly (and in any event not more than [*] after receipt of the Indemnitee's original notice) notify the Indemnitee in writing that it acknowledges its obligation (which acknowledgment shall not be deemed or construed as an admission of liability, either under this ARTICLE 10 or otherwise) to indemnify the Indemnitee with respect to the Claim pursuant to this ARTICLE 10 and of its intention to compromise or defend such Claim. As to all Claims as to which the Indemnifying Party has assumed control under this Section 10.3(b), the Indemnitee shall have the right to employ separate counsel and to participate in the defense of a Claim (as reasonably directed by the Indemnifying Party) at its own expense.

(c) Cooperation. The Indemnitee will cooperate fully with the Indemnifying Party and its legal representatives in the investigation and defense of any Claim. The Indemnifying Party shall keep the Indemnitee informed on a reasonable and timely basis as to the status of such Claim (to the extent the Indemnitee is not participating in the defense of such Claim) and conduct the defense of such Claim in a prudent manner.

(d) Settlement. If an Indemnifying Party assumes the defense of a Claim, no compromise or settlement of such Claim may be effected by the Indemnifying Party without the Indemnitee's written consent (such consent not to be unreasonably withheld, delayed or conditioned), unless: [*]. If the Indemnifying Party fails to assume defense of a Claim within [*], the Indemnitee may settle such Claim on such terms as it deems appropriate with the consent of the Indemnifying Party (such consent not to be unreasonably withheld, delayed or conditioned), and the Indemnifying Party shall be obligated to indemnify the Indemnitee for such settlement as provided in this ARTICLE 10.

10.4 Insurance. Each Party shall, at its own expense, procure and maintain during the Term and for a period of [*] thereafter, insurance policy/policies adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated. Such insurance shall not be construed to create a limit of a Party's liability with respect to its indemnification obligations under this ARTICLE 10. Each Party shall provide the other Party with prompt written notice of cancellation, non-renewal or material change in such insurance that could materially adversely affect the rights of such other Party hereunder and shall provide such notice within [*] after any such cancellation, non-renewal or material change.

10.5 Limitation of Liability. EXCEPT FOR A PARTY'S OBLIGATIONS SET FORTH IN THIS ARTICLE 10, INCLUDING BUT NOT LIMITED TO ANY DAMAGES REQUIRED TO BE PAID TO A THIRD PARTY PURSUANT TO A NON-APPEALABLE ORDER OF A COURT OF COMPETENT JURISDICTION IN CONNECTION WITH A THIRD PARTY CLAIM FOR WHICH THE INDEMNIFIED PARTY IS ENTITLED TO INDEMNIFICATION HEREUNDER; ANY BREACH OF SECTION 4.6 (EXCLUSIVITY); AND ANY BREACH OF

ARTICLE 8 (CONFIDENTIALITY), IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY (OR THE OTHER PARTY'S AFFILIATES OR SUBLICENSEES) IN CONNECTION WITH THIS AGREEMENT FOR LOST REVENUE, LOST PROFITS, LOST ROYALTIES, LOST SAVINGS, LOSS OF USE, DAMAGE TO GOODWILL, OR ANY CONSEQUENTIAL, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR INDIRECT DAMAGES UNDER ANY THEORY, INCLUDING CONTRACT, NEGLIGENCE, OR STRICT LIABILITY, EVEN IF THAT PARTY HAS BEEN PLACED ON NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

ARTICLE 11
MISCELLANEOUS

11.1 Notices. All notices and other communications given or made pursuant hereto shall be in writing and shall be deemed to have been duly given on the date delivered, if delivered personally, or on the next Business Day after being sent by reputable international overnight courier (with delivery tracking provided, signature required and delivery prepaid), or on the date sent and confirmed by E-mail, in each case, to the address specified below (or at such other addresses for such Party as may be specified by notice given in accordance with this Section 11.1).

(a) If to Olema:

Olema Pharmaceuticals, Inc.
512 2nd St, 4th Floor
San Francisco, CA 94107
Attention: Chief Business Officer

with a copy to:

Olema Pharmaceuticals, Inc.
512 2nd St, 4th Floor
San Francisco, CA 94107
Attention: Chief Legal Officer
Email: [*]

(b) If to Aurigene:

Aurigene Discovery Technologies Limited
39-40, KIADB Industrial Area Phase II,
Electronic City Hosur Road
Bangalore - 560100 Karnataka India
Attn: Murali Ramachandra, Chief Executive Officer

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

11.2 Governing Law.

(a) This Agreement and all disputes arising out of or related to this Agreement or any breach hereof shall be governed by and construed under the laws of the State of New York, without giving effect to any choice of law principles that would require the application of the laws of a different state. Any action or proceeding with respect to this Agreement must be brought in the state or federal courts located in Manhattan, New York, and each Party hereto submits with regard to any action or proceeding to the sole and exclusive jurisdiction of the aforesaid courts; provided that if the aforesaid courts are not a proper venue for seeking specific performance or injunctive relief, then either Party may bring an action or proceeding seeking specific performance or injunctive relief in a court of proper venue.

(b) Prior to initiating any action or proceeding with respect to this Agreement, such matter shall be referred to the Executive Officers for discussion and resolution within [*] from the date that the matter is first referred to the Executive Officers. If the Executive Officers are not able to resolve the matter within the [*] period, then either Party may initiate an action or proceeding as set forth in Section 11.2(a). Notwithstanding the foregoing, a Party shall be entitled to immediately seek specific performance or injunctive relief as a remedy without first submitting the matter for resolution by the Executive Officers in accordance with this Section 11.2(b).

11.3 Dispute Resolution.

(a) Except with respect to any dispute for which Olema has final decision-making authority under Section 2.5 and any dispute to be resolved as set forth in Section 11.3(b), any dispute relating to this Agreement shall be resolved in accordance with Section 11.2.

(b) If the Parties are unable to resolve a dispute regarding [*], then such dispute will resolved by "baseball arbitration" in accordance with this Section 11.3, by either Party sending written notice requesting such arbitration to the other Party.

(c) Baseball arbitration will be conducted by an expert panel. Within [*] following receipt of any notice requiring dispute resolution pursuant to this Section 11.3, each Party shall select [*] expert for such panel and the [*] experts selected by the Parties shall select a [*] expert for the panel within [*].

(d) Within [*] after the panel of experts are selected, each Party will deliver to both the expert panel and the other Party a detailed written proposal setting forth its proposed detailed terms to resolve the dispute, which with respect to Section 9.7(b)(4) or Section 9.7(c)(2) shall mean the complete license agreement ready for signature (the "**Proposed Terms**"), and a memorandum

in support thereof, not exceeding [*] in length (each, a "**Support Memorandum**"). The Parties will also provide the expert panel a copy of this Agreement, as may be amended at such time.

(e) Within [*] after receipt of the other Party's Proposed Terms and Support Memorandum, each Party may submit to the expert panel (with a copy to the other Party) a response to the other Party's Support Memorandum, such response not exceeding [*] in length (each, a "**Response Memorandum**"). Neither Party may have any other communications (either written or oral) with the expert panel other than for the sole purpose of engaging the expert panel or as expressly permitted in this Section 11.3; provided that the expert panel may convene a hearing if the expert panel so chooses to ask questions to the Parties and hear oral arguments and discussion regarding each Party's Proposed Terms.

(f) Within [*] after the expert panel's receipt of both Party's Response Memoranda, the expert panel will select one of the two Proposed Terms (without modification) provided by the Parties that the expert panel believes is most consistent with the intention underlying and agreed principles set forth in this Agreement. The decision of the expert panel shall be final, binding, and unappealable[*]. The expert panel must select as the only method to resolve the dispute at issue one of the two sets of Proposed Terms and may not combine elements of both Proposed Terms or award any other relief or take any other action.

11.4 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that a Party may make such an assignment of its rights and obligations hereunder in whole or in part without the other Party's consent to an Affiliate or to a successor to substantially all of the business of such Party to which this Agreement relates, whether in a merger, sale of stock, sale of assets or other transaction [*]. Any successor or assignee of rights and/or obligations permitted hereunder shall, in writing to the other Party, expressly assume performance of such rights and/or obligations. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section shall be null, void and of no legal effect. For purposes of clarity, each Party agrees that notwithstanding any provisions of this Agreement to the contrary, if either Party undergoes a Change of Control, such Change of Control shall not provide the other Party with any rights or access to the intellectual property or technology Controlled by the Party's Third Party successor or acquiror[*]

11.5 Designation of Affiliates. Each Party may discharge any obligation and exercise any right hereunder through delegation of its obligations or rights to any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

11.6 Relationship of the Parties. It is expressly agreed that Olema, on the one hand, and Aurigene, on the other hand, shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Olema nor Aurigene shall have the authority to make any statements, representations or commitments of any kind, or to take any action which shall be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of that Party and not of the other Party and all costs and obligations incurred by reason of such employment shall be for the account and expense of such Party.

11.7 Force Majeure. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by Force Majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting Force Majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a Force Majeure affecting such Party. If a Force Majeure persists for more than [*], then the Parties shall discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such Force Majeure. In the event a Party is prevented from performing its obligations under this Agreement due to Force Majeure for more than [*] according to this Section 11.7, the other Party shall have the right to terminate this Agreement upon [*] notice after the expiration of such period. [*]

11.8 Entire Agreement. This Agreement, including the Exhibits hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior and contemporaneous agreements and understandings between the Parties with respect to the subject matter hereof; provided, that the Confidential Disclosure Agreement shall be superseded and terminated hereby, with all Confidential Information disclosed thereunder being deemed Confidential Information under this Agreement. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party. In the event of any inconsistency between the body of this Agreement and either any Exhibits to this Agreement or any subsequent agreements ancillary to this Agreement, unless otherwise expressly stated to the contrary in such Exhibit or ancillary agreement, the terms contained in this Agreement shall control.

11.9 Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid

or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

11.10 English Language. This Agreement shall be written in and executed in, and all other communications under or in connection with this Agreement, shall be in the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

11.11 Waiver and Non-Exclusion of Remedies. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

11.12 Further Assurance. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof.

11.13 Headings. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

11.14 Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural shall include the singular, and the use of any gender shall be applicable to all genders. Whenever this Agreement refers to a number of days without using a term otherwise defined herein, such number refers to calendar days. The terms “including,” “include,” “includes” or “for example” shall not limit the generality of any description preceding such term and, as used herein, shall have the same meaning as “including, but not limited to,” and/or “including, without limitation.” The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof.

11.15 No Third Party Beneficiary Rights. This Agreement is not intended to and shall not be construed to give any Third Party any interest or rights (including any Third Party beneficiary

rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby, except as otherwise expressly provided for in this Agreement.

11.16 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by .pdf or other electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were the original signatures.

11.17 Expenses. Each Party shall pay its own costs, charges and expenses incurred in connection with the negotiation, preparation, and execution of this Agreement.

SIGNATURE PAGE FOLLOWS

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IN WITNESS WHEREOF, the Parties have signed this Agreement as of the Effective Date.

OLEMA PHARMACEUTICALS, INC.

By: /s/ Sean Bohen
Name: Sean Bohen
Title: CEO and President

AURIGENE DISCOVERY TECHNOLOGIES LIMITED.

By: /s/ Murali Ramachandra
Name: Murali Ramachandra
Title: CEO

*[*]*

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Exhibit A

Aurigene Patents

[*]

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Exhibit B

Olema Patents

[*]

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Exhibit C

Research Plan and Budget

[*]

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Exhibit D

Aurigene Compounds and Aurigene Materials

[*]

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Exhibit E

Press Release

[*]

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Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Sean Bohen, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 9, 2022

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

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Shane Kovacs, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 9, 2022

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

Exhibit 32.1

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

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

(1) The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2022, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Date: August 9, 2022

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

Date: August 9, 2022

By: /s/ Shane Kovacs
Shane Kovacs
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."