Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2023

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 May 5, 2023, the number of outstanding shares of the Registrant's common stock was 40,761,714.

Table of Contents

PART I-FINANCIAL INFORMATION

Item 1. Financial Statements.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements.

Olema Pharmaceuticals, Inc.

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

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 40,918	$ 23,702
Marketable securities	145,036	180,719
Prepaid expenses and other current assets	3,443	4,478
Total current assets	189,397	208,899
Property and equipment, net	1,380	1,480
Operating lease right-of-use assets	2,220	2,495
Other assets	2,771	2,771
Total assets	$ 195,768	$ 215,645
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 681	$ 374
Operating lease liabilities, current	908	1,015
Other current liabilities	17,821	15,160
Total current liabilities	19,410	16,549
Operating lease liabilities, net of current portion	1,383	1,550
Total liabilities	20,793	18,099
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of March 31, 2023 and December 31, 2022; no shares issued and outstanding as of March 31, 2023 and December 31, 2022.	—	—
Common stock, $0.0001 par value; 490,000,000 shares authorized as of March 31, 2023 and December 31, 2022; 40,696,563 and 40,601,648 shares issued as of March 31, 2023 and December 31, 2022, respectively; 40,438,320 and 40,287,097 shares outstanding as of March 31, 2023 and December 31, 2022, respectively.	3	3
Additional paid-in capital	413,213	408,333
Accumulated other comprehensive loss	(978)	(1,813)
Accumulated deficit	(237,263)	(208,977)
Total stockholders' equity	174,975	197,546
Total liabilities and stockholders' equity	$ 195,768	$ 215,645

See accompanying notes to the condensed consolidated financial statements.

Olema Pharmaceuticals, Inc.

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

	Three Months Ended March 31,	
	2023	2022
Operating expenses:		
Research and development	$ 22,826	$ 16,009
General and administrative	6,776	7,245
Total operating expenses	29,602	23,254
Loss from operations	(29,602)	(23,254)
Other income:		
Interest income	1,305	218
Other income:	11	6
Total other income	1,316	224
Net loss attributable to common stockholders	$ (28,286)	$ (23,030)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.70)	$ (0.58)
Weighted average shares used to compute net loss per share attributable to common stockholders, basic and diluted	40,354,493	39,834,619

	Three Months Ended March 31,	
	2023	2022
Net loss	$ (28,286)	$ (23,030)
Other comprehensive gain (loss):		
Net unrealized gain (loss) on marketable securities	835	(1,477)
Total comprehensive loss	$ (27,451)	$ (24,507)

See accompanying notes to the condensed consolidated financial statements.

Olema Pharmaceuticals, Inc.

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Gain	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2022	40,287,097	$ 3	$ 408,333	$ (1,813)	$ (208,977)	$ 197,546
Vesting of early exercised stock options	6,990	—	30	—	—	30
Vesting of restricted stock awards	49,318	—	—	—	—	—
Exercise of stock options	94,915	—	220	—	—	220
Stock-based compensation expense	—	—	4,515	—	—	4,515
Employee stock purchase plan expense	—	—	115	—	—	115
Net unrealized gain on marketable securities	—	—	—	835	—	835
Net loss	—	—	—	—	(28,286)	(28,286)
Balances at March 31, 2023	40,438,320	$ 3	$ 413,213	$ (978)	$ (237,263)	$ 174,975

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2021	39,797,263	$ 3	$ 388,904	$ (149)	$ (104,190)	$ 284,568
Vesting of early exercised stock options	6,989	—	31	—	—	31
Vesting of restricted stock awards	49,318	—	—	—	—	—
Exercise of stock options	15,755	—	33	—	—	33
Stock-based compensation expense	—	—	4,874	—	—	4,874
Employee stock purchase plan expense	—	—	91	—	—	91
Net unrealized loss on marketable securities	—	—	—	(1,477)	—	(1,477)
Net loss	—	—	—	—	(23,030)	(23,030)
Balances at March 31, 2022	39,869,325	$ 3	$ 393,933	$ (1,626)	$ (127,220)	$ 265,090

See accompanying notes to the condensed consolidated financial statements.

Olema Pharmaceuticals, Inc.

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

	Three Months Ended March 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (28,286)	$ (23,030)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	100	84
Non-cash lease expense	327	323
Premium amortization and discount accretion on marketable securities, net	(869)	6
Stock-based compensation expense, including employee stock purchase plan expense	4,630	4,965
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,035	172
Other assets	—	(240)
Accounts payable	307	245
Other current liabilities	2,691	(113)
Operating lease liabilities	(326)	(315)
Net cash used in operating activities	(20,391)	(17,903)
Cash flows from investing activities:		
Purchase of equipment	—	(30)
Maturities of marketable securities	61,760	148,750
Purchases of marketable securities	(24,373)	(123,153)
Net cash provided by investing activities	37,387	25,567
Cash flows from financing activities:		
Proceeds from exercise of stock options	220	33
Net cash provided by financing activities	220	33
Net increase in cash and cash equivalents	17,216	7,697
Cash and cash equivalents at beginning of period	23,702	13,812
Cash and cash equivalents at end of period	$ 40,918	$ 21,509
Supplemental disclosure of non-cash investing and financing activities:		
Reclassification of prepaid expenses and other current liabilities into other assets	$ —	$ 2,014

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 study, and in Phase 1b/2 clinical studies in combination with palbociclib, ribociclib, and alpelisib, 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. Olema Oncology Australia Pty Ltd was incorporated on January 6, 2021 and is a wholly-owned subsidiary of the Company (collectively with Olema Pharmaceuticals, Inc. referred to as "Olema" or the "Company" herein). It operates in one business segment and therefore has only one reportable segment. The Company is subject to risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including, but not limited to, successful discovery and development of its product candidates, development by competitors of new technological innovations, dependence on key personnel, the ability to attract and retain qualified employees, protection of proprietary technology, compliance with governmental regulations, the impact of geopolitical and macroeconomic events, such as the COVID-19 pandemic, ongoing conflict between Ukraine and Russia and related sanctions, recent and potential future bank failures and financial instability, 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 $186.0 million of cash, cash equivalents and marketable securities at March 31, 2023, which management believes is sufficient to fund its operating expenses and capital expenditure requirements into 2025.

Impact of Geopolitical and Macroeconomic Events

Global economic and business activities continue to face widespread geopolitical and macroeconomic uncertainties, including labor shortages, inflation and monetary supply shifts, bank failures and related financial market risks and instability, recession risks, as well as potential disruptions from the Russia-Ukraine conflict, which has resulted in volatility in the U.S. and global financial markets and which has led to, and may continue to lead to, additional disruptions to trade, commerce, pricing stability, credit availability and supply chain continuity globally. The extent of the impact of these factors on the Company's operational and financial performance, including its ability to execute its business strategies and initiatives in the expected time frame, will depend on future developments, which are uncertain and cannot be predicted. Any continued or renewed disruption resulting from these factors could negatively impact the Company's business. The Company

continues to monitor the impact of these geopolitical and macroeconomic factors on its results of operations, financial condition and cash flows.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

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

Unaudited Interim Financial Information

The interim condensed consolidated balance sheet as of March 31, 2023, and the statements of operations and comprehensive loss, stockholders' equity and cash flows for the three months ended March 31, 2023 and 2022 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-month periods are also unaudited. The results of operations for the three months ended March 31, 2023 are not necessarily indicative of the results to be expected for the year ending December 31, 2023 or for any other future annual or interim period. The condensed consolidated balance sheet as of December 31, 2022 included herein was derived from the audited financial statements as of that date. These interim condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements included in the Company's Form 10-K as filed with the SEC on March 9, 2023 (the "Annual Report").

Use of Estimates

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

Cash and Cash Equivalents

Cash and cash equivalents are defined as short-term, highly liquid investments with original maturities of 90 days or less at the date of purchase. Cash deposits are all in reputable financial institutions in the United States as of March 31, 2023 and December 31, 2022. Cash and cash equivalents consisted of cash on deposit with U.S. banks, including the Company's bank account for its Australia subsidiary, denominated in U.S. dollars and Australian dollars and investments in interest bearing money market funds.

Marketable Securities

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

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

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

Concentration of Credit Risk and Other Risks and Uncertainties

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

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

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

Leases

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

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

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

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

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

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred to discover, research and develop product candidates. These costs are recorded within research and development expenses in the condensed consolidated statements of operations and include personnel expenses, stock-based compensation expenses, allocated general and administrative expenses, and external costs including fees paid to consultants and 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 that do not meet the definition of a business are charged immediately to research and development expense if the technology licensed has not reached technological feasibility and has no alternative future uses.

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

Research Contract Costs and Accruals

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

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

Net Loss Per Common Share

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

Recent Accounting Pronouncements

There were no new accounting pronouncements that were relevant to the Company as of and for the three months ended March 31, 2023.

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.

	March 31, 2023			
(in thousands)	Level 1	Level 2	Level 3	Total
Financial Assets				
Cash	$ 6,688	$ —	$ —	$ 6,688
Money market funds	31,284	—	—	31,284
Commercial paper	—	76,463	—	76,463
U.S. government treasury bills	57,697	—	—	57,697
Government-sponsored enterprise securities	—	13,876	—	13,876
Total	$ 95,669	$ 90,339	$ —	$ 186,008

	March 31, 2023			
(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Financial Assets				
Cash and cash equivalents	$ 40,970	$ 1	$ —	$ 40,971
Short-term marketable securities (<12 months to maturity)	146,016	4	(983)	145,037
Total	$ 186,986	$ 5	$ (983)	$ 186,008

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. As of March 31, 2023, the Company does not have any marketable securities with maturities beyond one year.

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

There were 23 marketable securities that have been in a consecutive loss position for more than 12 months as of March 31, 2023. They had $0.8 million unrealized loss with a fair value of $63.7 million as of March 31, 2023. The Company does not believe that the total unrealized losses of $1.0 million as of March 31, 2023 are credit-related but are rather a reflection of current market yields and/or current marketplace bid/ask spreads. During the three months ended March 31, 2023 and 2022, respectively, the Company did not recognize any other-than-temporary impairment loss. As of March 31, 2023, there was no allowance for losses on available-for-sale debt securities attributable to credit risk.

As of March 31, 2023, 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):

	March 31, 2023	December 31, 2022
Lab equipment	$ 2,002	$ 2,002
Computer equipment	59	59
Property and equipment, gross	2,061	2,061
Less: Accumulated depreciation	(681)	(581)
Property and equipment, net	$ 1,380	$ 1,480

5. Prepaid Expenses and Other Current Assets

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

	March 31, 2023	December 31, 2022
Prepaid insurance	$ 1,254	$ 1,738
Reimbursable research and development costs from a collaboration partner	976	1,387
Prepaid clinical development costs	439	506
Prepaid subscriptions and licenses	400	399
Interest receivable	302	319
Other	72	129
Total	$ 3,443	$ 4,478

6. Other Current Liabilities

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

	March 31, 2023	December 31, 2022
Accrued research and development related costs	$ 12,080	$ 9,105
Accrued payroll related costs	2,741	296
Accrued professional fees	1,758	1,091
Accrued employee bonuses	1,082	4,518
Accrued taxes	109	68
Early exercise of unvested stock options	51	82
Total	$ 17,821	$ 15,160

7. Stock-Based Compensation

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

In 2020, the Company's Board of Directors and stockholders approved and adopted the 2020 Equity Incentive Plan (the "2020 Plan"). The 2020 Plan permits the grant of options, restricted stock awards, stock appreciation rights, restricted stock unit awards, performance awards, and other awards. The maximum number of shares of common stock that 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.

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 2022 Inducement Plan permits the grant of options, restricted stock awards, stock appreciation rights, restricted stock unit awards, performance awards, and other awards.

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

Stock Option Valuation

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

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

	March 31, 2023	March 31, 2022
Risk-free interest rate	3.48%	1.69%
Expected term (in years)	6.08	6.06
Expected volatility	87.22%	79.17%
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, 2022	8,384,858	$ 8.59	8.30	$ 262
Granted	1,989,728	4.79	—	—
Exercised(1)	(101,905)	2.47	—	—
Forfeited	(436,837)	3.71	—	—
Outstanding as of March 31, 2023(2)	9,835,844	$ 8.10	8.27	$ 2,029
Options vested and exercisable as of March 31, 2023	4,105,812	$ 9.70	7.46	$ 1,117
Options expected to vest as of March 31, 2023	5,730,032	$ 6.96	8.86	$ 912

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

(2) Balance as of March 31, 2023 includes 11,650 unvested early exercised stock options.

Early Exercise of Stock Options

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 March 31, 2023.

Restricted Stock Awards

The following table summarizes the restricted stock activity under the 2014 Plan during the three months ended March 31, 2023:

	Number of Shares	Grant Date Fair Value
Unvested restricted stock as of December 31, 2022	295,911	$ 2.40
Granted	—	—
Vested	(49,318)	2.40
Forfeited	—	—
Unvested restricted stock as of March 31, 2023	246,593	$ 2.40

Performance-Based Restricted Stock Unit Awards

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

Expense recognition for PSUs commences when it is determined that attainment of the performance goal is probable or met. As of March 31, 2023, it was determined that the performance goals were not yet met, and therefore, the Company recorded zero stock-based compensation expense related to the PSUs for the three months ended March 31, 2023.

2020 Employee Stock Purchase Plan

In 2020, the Company's Board of Directors and stockholders approved and adopted the ESPP. The ESPP permits eligible employees who elect to participate in an offering under the ESPP to have up to 15% of their eligible earnings withheld, subject to certain limitations, to purchase shares of common stock pursuant to the ESPP. The price of the common stock purchased under the ESPP is equal to the lesser of (i) 85% of the fair market value of a share of the Company's common stock on the first day of an offering; or (ii) 85% of the fair market value of a share of the Company's common stock on the date of purchase. Each offering period is not to exceed 27 months and will include one or more purchase periods (each a "Purchase Period") as approved by the Company's Board of Directors in the offering. The current offering period will consist of two (2) six-month Purchase Periods during which payroll deductions of the participants are accumulated under the ESPP. 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 $0.1 million for the three months ended March 31, 2023 and 2022, respectively.

Stock-Based Compensation Expense

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

	Three Months Ended March 31,	
	2023	2022
Research and development	$ 3,088	$ 3,067
General and administrative	1,542	1,898
Total	$ 4,630	$ 4,965

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 March 31,	
	2023	2022
Numerator:		
Net loss	$ (28,286)	$ (23,030)
Denominator:		
Weighted average shares used to compute net loss per share attributable to common stockholders, basic and diluted	40,354,493	39,834,619
Net loss per share attributable to common stockholders, basic and diluted	$ (0.70)	$ (0.58)

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:

	Three Months Ended March 31,	
	2023	2022
Unvested restricted common stock	246,593	443,867
Unvested performance-based restricted stock unit awards outstanding	710,000	—
Options to purchase common stock	9,835,844	8,368,353
Employee stock purchase plan contingently issuable	247,993	110,877
	11,040,430	8,923,097

Included in the potentially dilutive options to purchase common stock are 11,650 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 months ended March 31, 2023 and 2022.

9. Lease

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 agreement term to November 2023. As part of the sixth amendment, the Company gained access to use 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 months ended March 31, 2023 and 2022, respectively (in thousands):

	Three Months Ended March 31	
	2023	2022
Straight-line operating lease expense	$ 327	$ 322
Short-term lease expense	53	60
Variable lease expense	10	10
Total operating lease expense	$ 390	$ 392

The following table summarizes supplemental cash flow information during the three months ended March 31, 2023 and 2022, respectively (in thousands):

	Three Months Ended March 31	
	2023	2022
Cash paid for amounts included measurement of lease liabilities:		
Operating cash flows from operating leases	$ 326	$ 315

The following table summarizes the Company's future minimum lease payments and reconciliation of lease liabilities as of March 31, 2023 (in thousands):

Years Ended December 31,	
2023 (from April 2023)	$ 860
2024	799
2025	822
2026	69
Total future minimum lease payments	2,550
Less: Interest	(259)
Total lease liabilities at present value	2,291
Lease liabilities, current	908
Lease liabilities, non-current	$ 1,383

The following table summarizes lease term and discount rate as of March 31, 2023:

	Three Months Ended March 31	
	2023	2022
Weighted-average remaining lease term (years)	2.57	3.46
Weighted-average discount rate	8.70%	8.65%

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") and on January 13, 2022, the Company entered into the amended and restated clinical collaboration and supply agreement with Novartis (as amended and restated, 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 ("PI3Kα") Inhibitor Piqray® (alpelisib) (collectively the "Novartis Study Drugs") as part of the Company's planned Phase 1b clinical study 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 months ended March 31, 2023 and 2022, costs reimbursable from Novartis were $0.5 million and $0 million, respectively. As of March 31, 2023, the receivable due from Novartis was $1.0 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. As part of the collaboration, the parties granted to each other a non-exclusive, royalty-free license under certain of the parties’ respective patent rights in the combination of IBRANCE® and OP-1250 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 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 accompanying condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2023, and 2022.

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 Company and Aurigene jointly own collaboration compounds and rights to any inventions made during the research term.

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

The $8.0 million upfront payment was incurred in June 2022 and recorded as research and development expense in the accompanying condensed consolidated statements of operations and comprehensive loss. Costs incurred and milestones payments due to Aurigene prior to regulatory approval are recognized as research and development expenses in the period incurred. Payments due to Aurigene upon or subsequent to regulatory approval will be accrued as a provision to cost of sales in the period when achievement of respective milestone target is probable. As of March 31, 2023, it was determined that it is not probable to achieve any of the milestone target, and therefore, the Company recorded zero expense related to the milestone for the three months ended March 31, 2023.

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 March 31, 2023, 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 March 31, 2023 and December 31, 2022, 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, 2022 filed with the U.S. Securities and Exchange Commission, or the SEC, on March 9, 2023, or our Annual Report on Form 10-K.

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

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of next generation targeted therapies for women's cancers. 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 anti-tumor activity in a range of preclinical xenograft models of breast cancer, including in ESR1 and PIK3CA mutations and central nervous system, or CNS, metastasis. In August 2020, we initiated an ongoing Phase 1/2 monotherapy dose escalation and expansion study 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 1a dose escalation portion of this study in November 2021, which provided proof-of-concept for OP-1250 as a monotherapy treatment for ER+/HER2- breast cancer. We reported additional monotherapy data from the Phase 1b dose expansion portion of this study in October 2022 and initiated the Phase 2 portion of the study. We anticipate presenting Phase 2 clinical data for OP-1250 as a monotherapy in the second half of 2023. In 2022, we also initiated Phase 1b/2 dose escalation and expansion studies evaluating OP-1250 in combination with CDK4/6 inhibitors palbociclib and ribociclib and phosphatidylinositol 3 kinase alpha, or PI3Kα inhibitor, alpelisib. In December 2022, we reported initial data from the Phase 1a dose escalation portion of the study in combination with palbociclib which demonstrated combinability including no drug-drug interaction, or DDI, between the two agents. We anticipate presenting results from the Phase 2 clinical study for OP-1250 in combination with palbociclib in the second quarter of

2023 and from the Phase 1b clinical study for OP-1250 in combination with ribociclib in the second half of 2023. In July 2022, we were granted Fast Track designation from the U.S. Food and Drug Administration, or the FDA, for OP-1250 for patients with ER+/HER2- metastatic breast cancer that has progressed following one or more lines of endocrine therapy with at least one line given in combination with a CDK4/6 inhibitor. Based on the clinical results we have achieved to date, we are advancing OP-1250 through to late stage clinical development both as a monotherapy and in combination with other targeted agents. 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. On March 9, 2023, we announced a corporate restructuring and portfolio prioritization to focus our resources on the late-stage clinical development of OP-1250 for the treatment of ER+/HER2- metastatic breast cancer.

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 March 31, 2023, we had cash, cash equivalents, and marketable securities of $186.0 million. Based on our current operating plan, we believe that our cash, cash equivalents, and marketable securities as of March 31, 2023 will be sufficient to fund our planned operating expenses and capital expenditure requirements into 2025.

We have incurred significant operating losses since the commencement of our operations. Our net losses were $28.3 million and $23.0 million for the three months ended March 31, 2023 and 2022, respectively. We expect to incur significant and increasing losses for the foreseeable future as we continue to advance our product candidate, make potential milestone payments to our licensors, and as we continue to operate as a public company. Our net losses may fluctuate significantly from period to period, depending on the timing of expenditures on our research and development activities. As of March 31, 2023, we had an accumulated deficit of $237.3 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.

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

We will require substantial additional funding to develop our product candidate 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 geopolitical and macroeconomic events, such as the COVID-19 pandemic, the ongoing conflict between Ukraine and Russia and related sanctions, and recent bank failures and financial stability. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations or financial condition, including requiring us to have to delay, reduce or eliminate our product development or future commercialization efforts. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our development efforts. We cannot provide assurance that we will ever be profitable or generate positive cash flow from operating activities.

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

Components of our results of operations

Revenue

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

Operating expenses

Research and development

Research and development expenses account for a significant portion of our operating expenses and consist primarily of external and internal expenses incurred in connection with the discovery and development of our product candidates. To date, our research and development expenses have related primarily to discovery efforts and 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 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 $22.8 million and $16.0 million for the three months ended March 31, 2023 and 2022, 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 continued acceptable safety profiles of our products following approval; and
- obtaining and retaining key research and development personnel.

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

General and administrative

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

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

Results of operations

Comparison of the three months ended March 31, 2023 and 2022

The following table summarizes our results of operations for the three months ended March 31, 2023 and 2022:

	Three Months Ended March 31, 2023	2022	$ Change
	(in thousands)		
Operating expenses:			
Research and development	$ 22,826	$ 16,009	$ 6,817
General and administrative	6,776	7,245	(469)
Total operating expenses	29,602	23,254	6,348
Loss from operations	(29,602)	(23,254)	(6,348)
Other income:			
Interest income	1,305	218	1,087
Other income	11	6	5
Total other income	1,316	224	1,092
Net loss	$ (28,286)	$ (23,030)	$ (5,256)

Research and development expenses

Research and development expenses for the three months ended March 31, 2023 were $22.8 million, compared to $16.0 million for the three months ended March 31, 2022. The increase of $6.8 million was primarily due to increased spending in (i) advancing the clinical development for our lead product candidate OP-1250 and the associated contract manufacturing costs, (ii) other nonclinical research and discovery program costs, and (iii) personnel-related costs, including a one-time restructuring charge of $1.8 million, of which $0.1 million relates to non-cash stock-based compensation expense.

General and administrative expenses

General and administrative expenses for the three months ended March 31, 2023 were $6.8 million compared to $7.2 million for the three months ended March 31, 2022. The decrease of $0.5 million was primarily due to lower corporate costs and personnel-related expenses, including non-cash stock-based compensation expense decrease of $0.4 million, which was offset by a one-time restructuring charge of $1.0 million.

Other income

Other income for the three months ended March 31, 2023 was $1.3 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 $28.3 million and $23.0 million for the three months ended March 31, 2023 and 2022, respectively. Through March 31, 2023, we had received aggregate gross proceeds of $393.4 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 Company's 2020 Employee Stock Purchase Plan, or ESPP.

As of March 31, 2023, we had $186.0 million in cash, cash equivalents and marketable securities. As of March 31, 2023, we had accumulated deficit of $237.3 million. We had no debt outstanding as of March 31, 2023.

We expect to incur significant expenses and operating losses for the foreseeable future as we advance the clinical development of OP-1250 and nonclinical studies. We expect that our research and development and general and administrative costs will increase in connection with conducting additional nonclinical studies and clinical trials for our current and future research programs and product candidates, contracting with CMOs to support nonclinical studies and clinical trials, expanding our intellectual property portfolio, 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 and material cash requirements

To date, we have not generated any revenue from product sales. We do not expect to generate any meaningful revenue unless and until we obtain regulatory approval of and commercialize any of our product candidates, and we do not know when, or if at all, that will occur. We expect our expenses to increase in connection with our ongoing activities, particularly as we initiate and conduct clinical trials of, and seek marketing approval for, OP-1250. In addition, if we obtain marketing approval for our product candidates, we expect to incur significant commercialization expenses related to program sales, marketing, manufacturing and distribution to the extent that such sales, marketing and distribution are not the responsibility of potential collaborators. Furthermore, we have incurred and expect to continue to incur additional costs associated with operating as a public company. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our development efforts.

We expect our cash, cash equivalents, and marketable securities as of March 31, 2023 will enable us to fund our operating expenses and capital expenditure requirements into 2025 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 stockholder. 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)	Three Months Ended March 31, 2023	2022
Net cash used in operating activities	$ (20,391)	$ (17,903)
Net cash provided by investing activities	37,387	25,567
Net cash provided by financing activities	220	33
Net increase in cash and cash equivalents	$ 17,216	$ 7,697

Operating activities

Net cash used in operating activities during the three months ended March 31, 2023 consisted primarily of our net loss of $28.3 million, offset by non-cash charges of $3.9 million and a net increase in net operating assets and liabilities of $4.0 million. The net loss consisted primarily of $22.8 million in research and development expenses and $6.8 million in general and administrative expenses. The non-cash charges consisted primarily of stock-based compensation of $4.6 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 $0.3 million. These non-cash expenses were partially offset by net discount accretion on our marketable securities of $0.9 million. The net increase in operating assets and liabilities was primarily due to (i) a net increase of $2.7 million in other current

liabilities, (ii) a net increase of $1.0 million in prepaid expenses and other current assets and (iii) a net increase of $0.3 million in accounts payable, which is primarily a result of timing of invoice payment.

Net cash used in operating activities during the three months ended March 31, 2022 consisted primarily of our net loss of $23.0 million, offset by non-cash charges of $5.1 million and a net increase in net operating assets and liabilities of $0.1 million. The net loss consisted primarily of $16.0 million in research and development expenses and $7.2 million in general and administrative expenses. The non-cash charges consisted primarily of stock-based compensation of $5.0 million and depreciation and amortization expenses of $0.1 million, and noncash lease expense of less than $0.1 million, net of cash payments of $0.3 million. The net increase in operating assets and liabilities was primarily due to (i) a net decrease of $0.2 million in prepaid expenses and other current assets and (ii) an increase of $0.2 million in accounts payable, which is primarily a result of timing of invoice payment. The changes are partially offset by (i) a net increase of $0.2 million in other assets and (ii) a net decrease of $0.1 million in other current liabilities.

Investing Activities

Net cash provided by investing activities during the three months ended March 31, 2023 was predominately due to maturities of marketable securities which was offset by the purchase of marketable securities.

Net cash provided by investing activities during the three months ended March 31, 2022 was predominately due to maturities of marketable securities which was offset by the purchase of marketable securities.

Financing activities

Net cash provided by financing activities during the three months ended March 31, 2023 represents $0.2 million from the exercise of stock options.

Net cash provided by financing activities during the three months ended March 31, 2022 represents less than $0.1 million from the exercise of stock options.

Contractual obligations and commitments

Refer to Note 10 of our notes to the condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q for further information. There have been no material changes outside the ordinary course of business during the three months ended March 31, 2023 to our commitments and contingencies disclosed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K for the year ended December 31, 2022 filed on March 9, 2023 with the SEC.

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 three months ended March 31, 2023, there were no material changes to our critical accounting policies and estimates as reported in our Annual Report on Form 10-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

During the three months ended March 31, 2023, 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 March 31, 2023, 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 March 31, 2023, 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 March 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II-OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

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

RISK FACTOR SUMMARY

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

- We have 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 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 may not realize the expected benefits from our recent corporate restructuring, portfolio prioritization, and workforce reduction and we may incur additional costs or other difficulties implementing such initiatives.
- 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.
- Unfavorable U.S. and global macroeconomic and geopolitical conditions could adversely affect our business, financial condition and results of operations.
- In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth. 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, 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.
- 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 a Phase 1/2 clinical study 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 FDA, the European Medicines Agency, or 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 March 31,2023, we had $186.0 million in cash, cash equivalents, and marketable securities. Based on our current operating plans, we believe that our cash, cash equivalents, and marketable securities as of March 31, 2023 will be sufficient to fund our operating expenses and capital expenditures requirements into 2025. Our estimate as to how long we expect our existing cash, cash equivalents and marketable securities to be able to continue to fund our operating expenses and capital expenditures requirements is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, including a 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 and the geopolitical and macroeconomic environment, generally, including economic uncertainty, the COVID-19 pandemic, the ongoing conflict between Ukraine and Russia and related sanctions, and recent bank failures and financial instability. 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, cash equivalents and marketable securities 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 geopolitical and macroeconomic events such as the COVID-19 pandemic and the ongoing conflict between Ukraine and Russia and related sanctions, could adversely increase our need to access capital and likewise, adversely impact our ability to access capital as and when needed. For example, inflation rates, particularly in the United States, have increased recently to levels not seen in years, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital on acceptable terms, if at all. In addition, the U.S. Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation, which, coupled with reduced government spending and volatility in financial markets may have the effect of heightening these risks and further increasing economic uncertainty. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts. We also could be required to seek collaborators for OP-1250 or any future product candidate at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

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

We have incurred net losses in each reporting period since our inception, have not generated any revenue from product sales to date and have financed our operations principally through our initial public offering and private financings. We have incurred net losses of $28.3 million and $23.0 million for the three months ended March 31, 2023 and 2022, respectively. We had an accumulated deficit of $237.3 million as of March 31, 2023. 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 three months ended March 31, 2023 and 2022 included elsewhere in this Quarterly Report on Form 10-Q have been prepared assuming we will continue as a going concern. However, we have incurred losses and negative cash flows from operations. As a development stage company, we expect to incur significant and increasing losses until regulatory approval is granted for 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 may not realize the expected benefits from our recent corporate restructuring, portfolio prioritization, and workforce reduction and we may incur additional costs or other difficulties implementing such initiatives.

In March 2023, we announced a corporate restructuring and portfolio prioritization to focus our resources on the late-stage clinical development of OP-1250 for the treatment of ER+/HER2- metastatic breast cancer. As part of this restructuring, our workforce was reduced by approximately 25%, affecting employees across research, early development, and general and administrative functions.

The restructuring and reduction in force may yield unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond our intended reduction in force, a reduction in morale among our remaining employees, and the risk that we may not achieve the anticipated benefits, all of which may have an adverse effect on our clinical activities and results of operations or financial condition. We incurred one-time accounting charges of approximately $2.8 million, $2.7 million of which was attributable to cash expenditures. We may also incur other charges, costs, future cash expenditures or impairments not currently contemplated due to events that may occur as a result of, or in connection with, the restructuring and reduction in workforce. In addition, we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees, where applicable. We may also discover that the reduction in force and cost cutting measures will make it difficult for us to pursue new opportunities and initiatives and require us to hire qualified replacement personnel, which may require us to incur additional and unanticipated costs and expenses. Moreover, there is no assurance we will be successful in our pursuit of any of our new goals. Our failure to successfully accomplish any of the above activities and goals may have a material adverse impact on our business, financial condition, results of operations, and ability to successfully develop OP-1250.

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 our product candidate 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 EMA's Committee for Medicinal Products for Human Use, 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 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.

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 stockholder value will be limited.

In addition, we may rely in part on nonclinical, clinical and quality data generated by CROs and other third parties for regulatory submissions for 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.

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.

Although we have received Fast Track designation for OP-1250 for ER+/HER2- metastatic breast cancer that has progressed following one or more lines of endocrine therapy with at least one line given in combination with a CDK4/6 inhibitor, we may be unable to obtain or maintain the benefits associated with such designation.

In July 2022, we were granted FDA Fast Track designation for OP-1250 for ER+/HER2- metastatic breast cancer that has progressed following one or more lines of endocrine therapy with at least one line given in combination with a CDK4/6 inhibitor. If a drug is intended for the treatment of a serious or life-threatening condition and demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for FDA Fast Track designation for a particular indication. NDAs submitted for Fast Track designated drugs may qualify for priority review, accelerated approval and rolling submission under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing approval by the FDA. In addition, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track designation does not provide assurance of ultimate FDA approval.

Because we are pursuing a variety of target indications for 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, in March 2023, we underwent a corporate restructuring and portfolio prioritization to focus our resources on late-stage clinical development of OP-1250. We also may in the future spend our resources on other research programs and product candidates for specific indications that ultimately do not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

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

Even if approved, 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.

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;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion or, because they may be late-stage cancer patients, will not survive the full terms of the clinical trials; and
- the level of resources that clinical sites have to conduct a growing number of clinical studies.

Our inability to enroll and maintain a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for OP-1250 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 study of OP-1250 in a combination trial with a cyclin-dependent kinase 4 and 6 inhibitor, and in the third quarter of 2022 we initiated Phase 1b clinical studies of OP-1250 in combination with another CDK4/6 inhibitor and with a PI3Kα 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 product candidates, and we may acquire or in-license potential product candidates for in the future, as we continue to build our pipeline. Such arrangements with third parties may impose diligence, development and commercialization obligations, milestone payments, royalty payments, indemnification and other obligations on us. Our obligations to pay milestone, royalty and other payments to our licensor may be substantial, and the amount and timing of such payments may impact our ability to progress the development and commercialization of our product 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 field of women's cancer which we are pursuing. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, emerging and start-up companies, government agencies, 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 or any generic equivalents of Faslodex® that are marketed or in development; elacestrant, marketed as ORSERDU™ by Stemline Therapeutics Inc.; giredestrant (GDC-9545), being developed by Roche Holding AG/Genentech, Inc.; camizestrant (AZD9833), being developed by AstraZeneca PLC; imlunestrant (LY3484356), being developed by Eli Lilly and Co.; ARV 471, being developed by Arvinas, Inc.; 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, or HHS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our product to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular products and requiring substitutions of generic products and/or biosimilars. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly examining the

medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA- approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our product. Nonetheless, 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 are developing and seeking approval. Furthermore, any regulatory approval to market a drug may be subject to significant limitations on the approved uses or indications for which we may market the drug or the labeling or other restrictions. In addition, the FDA has the authority to require a REMS as part of approving a NDA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. These requirements or restrictions might include limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may significantly limit the size of the market for the drug and affect reimbursement by third-party payors.

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

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. The 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 study, 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 delayed. 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. 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 verify and describe the drug's clinical benefit. Third-party payors may refuse to provide coverage or reimbursement for the drug until the confirmatory studies are complete. Additionally, if such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug.

Prior to seeking accelerated approval for 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. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. In addition, there have been a number of health reform initiatives by the Biden administration that have impacted the ACA. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect until 2032 unless additional congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. 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, in July 2021, the Biden administration released an executive order that included multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain high-expenditure single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. In addition, the Biden administration released an additional executive order on October 14, 2022, directing HHS to report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that the recent reform activity, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize OP-1250 or any future product candidates we may develop.

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

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

State and international laws 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 UK, 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 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 the UK. 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.

In addition, we may be unable to receive and/or further transfer onwards personal data that is processed subject to the EU GDPR and/or UK GDPR, or certain other data privacy and security regimes, due to limitations on cross-border data flows and/or actual or de facto data localization requirements. In particular, the EU GDPR and UK GDPR significantly restrict the transfer of personal data to the United States and other countries whose privacy laws are considered 'inadequate' for the purposes of either or both of those regulations. Although there are currently various mechanisms that may be used to effect such cross-border transfers of personal data in compliance with the EU GDPR and UK GDPR, such as the European Commission's 'Standard Contractual Clauses' and the United Kingdom's 'International Data Transfer Agreement / Addendum', all such mechanisms are subject to legal challenges, and there is no assurance that we can always satisfy or rely on these mechanisms to lawfully effect cross-border transfers of personal data where required.

Other jurisdictions relevant to our operations may implement, or adopt stringent interpretations of, their own data localization and cross-border data transfer laws. If there is no lawful manner for us to effect or be the recipient of cross-border transfers of personal data in compliance with the EU GDPR and/or UK GDPR, and/or other applicable data privacy and security obligations, or if the requirements for a compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data to recipients outside the EEA for allegedly violating the EU GDPR's cross-border data transfer limitations. Additionally, companies that transfer personal data to recipients outside of the EEA and/or UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators individual litigants and activist groups.

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

Additionally, California voters approved a new privacy law, the California Privacy Rights Act, or CPRA, which went into effect on January 1, 2023. The CPRA 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, Colorado, Utah and Connecticut all passed comprehensive privacy laws that have or will go into effect in 2023. While some of these state laws, like the CCPA, exempt some data processed in the context of clinical trials, these laws demonstrate our vulnerability to the evolving regulatory environment related to personal information and make it difficult to predict the impact of such laws on our business or operations. Aspects of these state privacy statutes remain unclear, resulting in further legal uncertainty and potentially requiring us to modify our data practices and policies and to incur substantial additional costs and expenses in an effort to comply.

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 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. 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. 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 of our systems or our third-party service providers 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.

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.

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

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

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

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

Our results of operations could be adversely affected by general conditions in the U.S. and global economies, the U.S. and global financial markets and adverse geopolitical and macroeconomic developments, including the COVID-19 pandemic, the ongoing conflict between Ukraine and Russia and related sanctions, and recent bank failures and financial instability. U.S. and global market and economic conditions have been, and continue to be, disrupted and volatile due to many factors, including component shortages and related supply chain challenges, geopolitical developments such as the ongoing COVID-19 pandemic, the ongoing conflict between Ukraine and Russia and related sanctions, recent bank failures and financial instability, increasing inflation rates and the responses by central banking authorities to control such inflation, among others. General business and economic conditions that could affect our business, financial condition or results of operations include fluctuations in economic growth, debt and equity capital markets, liquidity of the global financial markets, the availability and cost of credit, investor and consumer confidence, and the strength of the economies in which we, our manufacturers and our suppliers operate.

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

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

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

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

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

and commercialize 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 March 31, 2023, we had 63 employees, 62 of whom were full-time, including 36 employees engaged in research and development. In March 2023, we implemented a reduction in force, which reduced our workforce by approximately 25% as part of our corporate restructuring and prioritization. However, in order to successfully implement our development and commercialization plans and strategies, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA, EMA and other comparable foreign regulatory 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. We have in the past and may in the future be subject to security breaches. For instance, we have had company laptops containing corporate information stolen from company offices. 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, 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 study of OP-1250 at the San Antonio Breast Cancer Symposium. Additionally, the loss or compromise of clinical trial data from completed or future clinical trials could result in delays or revocation of our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. We also rely on third parties to manufacture 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.

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.

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.

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 Phase 1b clinical study 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 Phase 1b clinical study may be delayed and the cost to us to conduct this trial may significantly increase, which would significantly harm our business, financial condition, results of operations and prospects. For a description of the Novartis Agreement, see 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 engaged in the past and may in the future engage in or evaluate various acquisition opportunities, strategic partnerships and in-licensing opportunities, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management’s attention from our existing programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risk of delay in receiving or the failure to receive anticipated benefits of any such transactions, or of facing unanticipated challenges;

- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; and

- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

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

We have entered into collaborations with third parties for the development and commercialization of 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. For example, the closing price of our common stock from January 1, 2022 to May 5, 2023 has ranged from a low of $2.04 to a high of $9.43. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

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

- the timing and results of 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 geopolitical, macroeconomic, industry and market conditions, including the COVID-19 pandemic, the ongoing conflict between Ukraine and Russia and related sanctions, and recent bank failures and financial instability.

In addition, the trading prices for common stock of other biopharmaceutical companies have been highly volatile as a result of factors unrelated to the specific company or its technology, as well as due to the COVID-19 pandemic.

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

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

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

- timing and variations in the level of expense related to the ongoing development of OP-1250 or future development programs;
- timing and status of enrollment for our clinical trials;
- impacts from geopolitical and macroeconomic events on us or third parties with which we engage;
- results of clinical trials, or the addition or termination of clinical trials or funding support by us or potential future partners;
- our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under potential future arrangements or the termination or modification of any such potential future arrangements;
- any intellectual property infringement, misappropriation or violation lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if 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 March 31, 2023, we had 40,438,320 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.

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, or Section 404, presenting only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and presenting reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict whether investors will find our securities less attractive because we will rely on these exemptions. If some investors find our securities less attractive as a result of our reliance on these exemptions, the trading prices of our securities may be lower than they otherwise would be, there may be a less active trading market for our securities and the trading prices of our securities may be more volatile.

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

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

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 662⁄3% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our amended and restated certificate of incorporations or amended and restated bylaws.

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

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

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

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of fiduciary duty;

- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; and

- any action asserting a claim against us that is governed by the internal-affairs doctrine or otherwise related to our internal affairs.

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

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

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

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

General risk factors

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

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

condition, results of operations and prospects. We may also need to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

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

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

In addition, as a result of our disclosure obligations as a public company, our business and financial condition has become more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. 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, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Overall, we will continue with the implementation of additional measures around internal controls, and these will require validation and testing of the design and operating effectiveness of internal controls over a sustained period of financial reporting cycles. If we are unable to avoid future material weaknesses, our operations, financial reporting, or financial results could be harmed. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

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

The trading market for our common stock is influenced by the research and reports that securities or industry analysts publish about us, our business or our market. If any of the analysts who cover us issue adverse or

misleading research or reports regarding us, our business model, our intellectual property, our stock performance or our market, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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 stockholder 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.

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

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

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

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

Recent Sales of Unregistered Securities

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.

None.

Item 6. Exhibits.

		Incorporated by Reference			
Exhibit Number	Description	Schedule Form	File Number	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation.	8-K	001-39712	3.1	11/23/2020
3.2	Amended and Restated Bylaws.	8-K	001-39712	3.1	12/16/2022
10.1*¥	Amended and Restated Clinical Collaboration and Supply Agreement, by and between the Registrant and Novartis Institutes for BioMedical Research, Inc., dated January 13, 2022.				
10.2*#	Separation Agreement by and between the Registrant and Cyrus Harmon, dated March 21, 2023.				
10.3*#	Separation Agreement by and between the Registrant and Kinney Horn, dated March 8, 2023.				
31.1*	Certification of Chief Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Chief Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1*†	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL Document				
101.SCH*	Inline XBRL Taxonomy Extension Schema Document				
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document				

101.PRE*	Inline 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.
\# Indicates management contract or compensatory plan or arrangement.
† The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act or the Exchange Act, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.
¥ Pursuant to Item 601(b)(10) of Regulation S-K, portions of this exhibit have been omitted as the Registrant has determined that the omitted information is the type that the Registrant customarily and actually treats as private or confidential and is not material.

SIGNATURES

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

Olema Pharmaceuticals, Inc.

Date: May 9, 2023

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

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

Date: May 9, 2023

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 [***], has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

AMENDED AND RESTATED CLINICAL COLLABORATION AND SUPPLY AGREEMENT

This **AMENDED AND RESTATED CLINICAL COLLABORATION AND SUPPLY AGREEMENT** (the "***Agreement***") is made and entered into effective as of **January 13, 2022** (the "***Effective Date***") by and between **Olema Pharmaceuticals, Inc.,** a Delaware corporation, having a place of business at 665 3rd St, San Francisco, CA 94107 ("***Olema***"), and **Novartis Institutes for BioMedical Research, Inc.**, a Delaware corporation, having a place of business at 181 Massachusetts Avenue, Cambridge, MA 02139 ("***Novartis***"). Olema and Novartis are sometimes individually referred to in this Agreement as a "***Party***" and collectively as the "***Parties***."

PRELIMINARY STATEMENTS

A. Olema desires to conduct, and Novartis desires to supply the Novartis Study Drugs (as defined below) for the conduct of, a Combined Therapy Clinical Trial(s) (as defined below) in accordance with the Development Plan and applicable Protocol(s) (as defined below) and in accordance with the terms of this Agreement.

(b) The Parties are parties to that certain Clinical Collaboration and Supply Agreement, dated as of July 22, 2020 (the "Effective Date"), pursuant to which the Parties are collaborating with respect to the desire to agree on various terms and conditions to govern the Parties' respective rights and obligations in connection with the performance of the Combined Therapy Clinical Trials (the "Original Agreement") and the ownership and use of the results of such trial.

(c) The Parties now desire to amend and restate the Original Agreement to cover the Novartis Alpelisib Metabolite (as defined below).

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises and covenants contained herein, the Parties agree as follows:

ARTICLE 1

DEFINITIONS

The following terms in this Agreement with initial letters capitalized, whether used in the singular or the plural, shall have the meanings set forth below. If not listed below, terms with initial letters capitalized and defined elsewhere in places throughout this Agreement shall have the meanings designated in such definitions.

"***Adverse Event***" ("AE"), "***Serious Adverse Event***" ("SAE") and "***Serious Adverse Drug Reaction***" ("SADR") shall have the meanings provided to such terms in the International Conference on Harmonization ("ICH") guideline for industry on Clinical Safety Data Management (E2A, Definitions and Standards for Expedited Reporting).

"***Affiliate***" means, with respect to a particular Party, an entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with such Party. As used in this definition, the term "controls" (with correlative meanings for the terms "controlled by" or "under common control with") means: (a) that the applicable entity owns, directly or indirectly, more than fifty percent (50%) of the voting stock of the applicable Party, or (b) that the applicable entity otherwise has the actual ability to control and direct the management of the applicable Party, whether by contract or otherwise.

"***Agreement***" means this Agreement, and includes the Appendices attached hereto, the Quality Documentation and any and all written amendments of any of the foregoing hereafter executed by the Parties with reference to this Agreement and made part hereof.

"***Applicable Law***" means all applicable laws, rules and regulations (whether federal, state or local) that may be in effect from time to time, including current Good Clinical Practices (GCP), Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP).

"***Breaching Party***" shall have the meaning set forth in Section 11.2(a).

"***Budget***" means the mutually agreed estimated and anticipated costs for the Combined Therapy Clinical Trials as set forth on Appendix B.

"***Business Day***" means a day other than Saturday, Sunday or a Federal holiday on which commercial banks located in New York, NY, Cambridge, MA, or Basel, Switzerland are authorized or obligated by law to be closed.

"***CDA***" shall have the meaning set forth in Section 8.1(a).

"***Clinical Hold***" means that (a) the FDA has issued an order to a Party pursuant to 21 CFR §312.42 to delay a proposed clinical investigation or to suspend an ongoing clinical investigation of the Combined Therapy or such Party's Single Agent Compound in the United States or (b) a Regulatory Authority other than the FDA has issued an equivalent order to that set forth in (a) in any other country or group of countries.

"***Combined Therapy***" means a therapy using Olema Study Drug and the Novartis Study Drugs in combination.

"***Combined Therapy Clinical Trials***" means any and all human clinical trials of the Combined Therapy to be conducted by Olema pursuant to this Agreement, the Development Plan, and the applicable Protocol, and for clarity including specifically but limited to only separate clinical trials directed solely to the Combined Therapy.

"***Combined Therapy Clinical Trial IND***" shall have the meaning set forth in Section 2.1(c).

"***Combined Therapy Invention***" means any Study Invention that is not a Olema Study Invention or a Novartis Study Invention.

"***Combined Therapy Patent Right***" means any Patent Right that Covers a Combined Therapy Invention or Combined Therapy Study Data. For clarity, the Novartis Background Patent Rights and Olema Background Patent Rights are excluded from the term Combined Therapy Patent Right.

"***Combined Therapy Clinical Trial Regulatory Documentation***" means any Regulatory Documentation submitted by or on behalf of Olema for the conduct of the Combined Therapy Clinical Trials, but excluding (a) any Olema Regulatory Documentation and (b) any Novartis Regulatory Documentation.

"***Combined Therapy Study Data***" shall have the meaning set forth in Section 7.2.

"***Commercially Reasonable Efforts***" means, with respect to a Party, the level of effort and resources normally devoted by [***] to conduct or support the conduct (including manufacturing and supply of clinical materials) of a clinical trial for a biopharmaceutical product or compound that is owned by [***] or to which [***] has rights, which is of similar market potential, profit potential and strategic value and at a similar stage in its development or product life, based on conditions then prevailing.

"***Confidential Information***" shall have the meaning set forth in Section 8.1(a).

"***Control***" or "***Controlled***" means, with respect to particular Technology or intellectual property, that the applicable Party owns or has a license to such Technology or intellectual property (*other than* solely by a license granted to such Party by the other Party under this Agreement) and has the ability to grant a right, license or sublicense to the other Party as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.

"***Cover***" means, with respect to a particular Patent Right and a particular Technology, that the practice by an unauthorized Person of such Technology (including the manufacture, use or sale of such Technology) would infringe a claim included in such Patent Right, or in the case of a Patent Right that is a patent application (i.e., that has not issued as a patent), would infringe a claim in such patent application if it were to issue as a patent. "***Covered***" or "***Covering***" shall have correlative meanings.

"***CRO***" means any Third Party contract research organization used to conduct or assist in the conduct of the Combined Therapy Clinical Trials, including laboratories and Third Parties used to maintain the safety database from the Combined Therapy Clinical Trials, but, for clarity, excluding the Trial Sites.

"***Cure Period***" shall have the meaning set forth in Section 11.2(a).

"***Date of First Receipt***" means, with respect to a Party, the date on which any employee of such Party, its Affiliates or its Third Party subcontractors first becomes aware of applicable safety-related information.

"***Development Plan***" means the plan specifying each Party's general tasks and activities for the conduct of the Combination Therapy Clinical Trials, as agreed by the Parties, and as such plan may be amended or modified by the Parties in writing; a copy of the agreed Development Plan will be attached as Appendix A of this Agreement in accordance with Section 2.2.

"***Designated Clinical Contact***" shall have the meaning set forth in Section 2.4.

"***Designated Supply Contact***" shall have the meaning set forth in Section 4.7.

"***Direct Outside Costs***" means the direct costs set forth in the Budget incurred by Olema in conducting activities under the Development Plan to conduct the Combined Therapy Clinical Trials, such costs to include [***].

"***Dispute***" shall have the meaning set forth in Section 12.3(b).

"***Effective Date***" shall have the meaning set forth in the preamble to this Agreement.

"***Executive Officers***" means the [***] of Olema and the [***] of Novartis (or their respective designees).

"***FDA***" means the United States Food and Drug Administration, or any successor agency having the same or similar authority.

"***Final Study Report***" shall have the meaning ascribed to such term in Section 2.1.

"***Final Results Date***" means the date that the Results have been delivered to Novartis hereunder.

"***Global Safety Database***" means the database containing Adverse Events, Serious Adverse Events, Serious Adverse Drug Reactions and pregnancy reports for the Combined Therapy, and shall be the authoritative data source for regulatory reporting and responding to regulatory queries with respect to the Combined Therapy Clinical Trials.

"***Good Clinical Practices***" or "***GCP***" means, as to the United States and the European Union, applicable good clinical practices as in effect in the United States and the European Union, respectively,

during the Term and, with respect to any other jurisdiction, clinical practices equivalent to good clinical practices as then in effect in the United States or the European Union.

"***Good Laboratory Practices***" or "***GLP***" means, as to the United States and the European Union, applicable good laboratory practices as in effect in the United States and the European Union, respectively, during the Term and, with respect to any other jurisdiction, laboratory practices equivalent to good laboratory practices as then in effect in the United States or the European Union.

"***Good Manufacturing Practices***" or "***GMP***" means, as to the United States and the European Union, applicable good manufacturing practices as in effect in the United States and the European Union, respectively, during the Term and, with respect to any other jurisdiction, manufacturing practices equivalent to good manufacturing practices as then in effect in the United States or the European Union.

"***ICF***" shall have the meaning set forth in Section 5.1(f).

"***IND***" means (a) an Investigational New Drug Application as defined in the United States Food, Drug and Cosmetic Act, as amended, and regulations promulgated thereunder, or any successor application or procedure required to initiate clinical testing of a drug in humans in the United States, (b) a counterpart of such an Investigational New Drug Application that is required in any other country before beginning clinical testing of a drug in humans in such country, including, for clarity, a "***Clinical Trial Application***" in the European Union, and (c) all supplements and amendments to any of the foregoing.

"***Indemnify***" shall have the meaning set forth in Section 10.1.

"***Infringe***" and "***Infringement***" means any infringement, or written allegation of infringement, by a Third Party, of applicable Patent Rights.

"Invoice" shall have the meaning set forth in Section 5.3.

"***IRB***" means an Investigational Review Board or Ethics Committee (or similar body in a given country).

"***Losses***" shall have the meaning set forth in Section 10.1.

"***Manufacture"*** or "***Manufacturing***" means manufacturing, processing, formulating, packaging, labeling, holding (including storage), and quality control testing of a Single Agent Compound or the Combined Therapy, in each case so as to be suitable for use in the Combined Therapy Clinical Trials under Applicable Law.

"***Material Safety Issue***" means a Party's reasonable, good faith belief that there is an unacceptable risk for harm in humans based upon: (a) [***], or (b) [***].

"***NDA***" means (a) any new drug application or biologics license application filed with the FDA, or any successor application or procedure required to introduce a drug or biologic into commerce in the United States, (b) a counterpart of such a new drug application or biologics license application that is required in any other country before beginning the commercialization of a drug or a biologic in humans in such country, and (c) all supplements and amendments to any of the foregoing.

"***Non-Breaching Party***" shall have the meaning set forth in Section 11.2(a).

"Novartis Alpelisib Metabolite" means Novartis' proprietary metabolite or derivative compound BZG791, and any drug candidate or product containing BZG791.

"***Novartis Background Patent Right***" means a Patent Right that: (a) is Controlled by Novartis (or any of its Affiliates) (i) as of the Effective Date, or (ii) during the Term that claims an invention that was conceived or first reduced to practice through activities other than those performed pursuant to this

Agreement, and (b) Covers the use (whether alone or in combination with other agents), manufacture, formulation or composition of matter of the Novartis Study Drugs or the Novartis Alpelisib Metabolite.

"***Novartis Background Technology***" means all Technology that is (a) Controlled by Novartis (or its Affiliates) (i) as of the Effective Date, or (ii) during the Term and created through efforts outside of this Agreement, (b) related to the Novartis Study Drugs, the Novartis Alpelisib Metabolite or the Combined Therapy, and (c) reasonably needed for the conduct of the Combined Therapy Clinical Trials and/or for Olema to exercise the rights that are granted to Olema under this Agreement. For clarity, all Study Inventions, Study Data, and Combined Therapy Clinical Trials Regulatory Documentation are excluded from the term Novartis Background Technology.

"***Novartis Indemnitees***" shall have the meaning set forth in Section 10.2.

"***Novartis Regulatory Documentation***" means any Regulatory Documentation of Novartis (or its Affiliate) pertaining to the Novartis Study Drugs or the Novartis Alpelisib Metabolite that exists as of the Effective Date or that is created during the Term through efforts outside this Agreement.

"***Novartis Study Data***" shall have the meaning set forth in Section 7.2.

"***Novartis Study Drugs***" means Novartis' proprietary CDK4/6 inhibitor Kisqali® (ribociclib, also known as LEE001), and/or Novartis' proprietary phosphatidylinositol 3-kinase inhibitor Piqray® (alpelisib, also known as BYL719), and any drug candidate or product containing Kisqali® and/or Piqray®.

"***Novartis Study Invention***" means any Study Invention that pertains to: (a) the composition of matter of the Novartis Study Drugs or the Novartis Alpelisib Metabolite (and, in each case, not Olema Study Drug), (b) a method of manufacture or formulation or administration, including dosing, of the Novartis Study Drugs (and not Olema Study Drug) or the Novartis Alpelisib Metabolite as a Single Agent Compound (and for clarity, not with respect to the Combined Therapy), (c) a method of use of the Novartis Study Drugs (and not Olema Study Drug) as a monotherapy or as used with other agents, antibodies or compounds (other than a Study Invention pertaining to use with Olema Study Drug), and/or (d) a method of use of the Novartis Alpelisib Metabolite as as a sole agent or as used with other agents, antibodies or compounds (other than a Study Invention pertaining to use with Olema Study Drug).

"***Novartis Study Patent Right***" means any Patent Right that Covers a Novartis Study Invention (and not an Olema Study Invention or Combined Therapy Invention), excluding Novartis Background Patent Rights and Novartis Background Technology. For avoidance of doubt, any Patent Rights that Cover both (a) a Novartis Study Invention and (b) any other type of Study Invention is included within the Combined Therapy Patent Rights and is not within the Novartis Study Patent Rights.

"***Officials***" shall have the meaning set forth in Section 9.9.

"***Olema Background Patent Right***" means any Patent Right (a) that is Controlled by Olema or a Olema Affiliate (i) as of the Effective Date, or (ii) during the Term that claims an invention that was conceived or first reduced to practice through activities other than those performed pursuant to this Agreement, and (b) that Covers the use (either alone or in combination with other agents), manufacture, formulation or composition of matter of Olema Study Drug.

"***Olema Background Technology***" means all Technology (a) that is Controlled by Olema (or its Affiliates) (i) as of the Effective Date, or (ii) during the Term and created through efforts outside of this Agreement, and (b) that is related directly to Olema Study Drug or the Combined Therapy, and (c) that is reasonably needed for the conduct of the Combined Therapy Clinical Trials and/or for Novartis to exercise the rights granted to Novartis under this Agreement. For clarity, all Study Inventions, Study Data, and Combined Therapy Clinical Trials Regulatory Documentation are excluded from the term Olema Background Technology.

"***Olema Indemnitees***" shall have the meaning set forth in Section 10.1.

"***Olema Regulatory Documentation***" means any and all Regulatory Documentation of Olema pertaining to Olema Study Drug that exists as of the Effective Date or that is created during the Term through efforts outside this Agreement.

"***Olema Study Data***" shall have the meaning set forth in Section 7.2.

"***Olema Study Drug***" means Olema's proprietary OP-1250 compound, or metabolite thereof, which inhibits estrogen receptor, including salts thereof, and any drug candidate or product containing such compound or the metabolite.

"***Olema Study Invention***" means any Study Invention that pertains to: (a) the composition of matter of Olema Study Drug (and not the Novartis Study Drugs or the Novartis Alpelisib Metabolite), (b) method of manufacture or formulation or administration, including dosing, of Olema Study Drug (and not the Novartis Study Drugs or the Novartis Alpelisib Metabolite) as a Single Agent Compound (and for clarity, not with respect to the Combined Therapy or in combination with the Novartis Alpelisib Metabolite), or (c) a method of use of Olema Study Drug (and not the Novartis Study Drugs or the Novartis Alpelisib Metabolite) as a monotherapy or as used in combination with other agents, antibodies or compounds (other than a Study Invention pertaining to use with the Novartis Study Drugs or the Novartis Alpelisib Metabolite).

"***Olema Study Patent Right***" means any Patent Right that Covers a Olema Study Invention (and not a Novartis Study Invention or a Combined Therapy Invention), excluding Olema Background Patent Rights and Olema Background Technology. For avoidance of doubt, any Patent Right that Covers both (a) an Olema Study Invention and (b) any other type of Study Invention is included within the Combined Therapy Patent Rights and is not within the Olema Study Patent Rights.

"***Operational Matters***" shall have the meaning set forth in Section 5.1.

"***Party***" or "***Parties***" shall have the meaning set forth in the preamble to this Agreement.

"***Patent Right***" means any (a) United States or foreign patent, (b) United States or foreign patent application, including all provisional applications, substitutions, continuations, continuations-in-part, divisions, and renewals (and all foreign equivalents of any of the foregoing), and all patents issued or granted on any such patent application, (c) United States or foreign patents-of-addition, reissues, reexaminations (including *ex parte* reexaminations, *inter partes* reviews, *inter partes* reexaminations, post grant reviews and supplemental examinations) and extensions or restorations by existing or future extension or restoration mechanisms, including supplementary protection certificates, patent term extensions and adjustments, or the equivalents thereof, and all foreign equivalents thereof, and (d) any other form of government-issued right substantially similar to any of the foregoing.

"***Payment***" shall have the meaning set forth in Section 9.9.

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

"***Personal Data***" means any information relating to an identified or identifiable natural person.

"***POTV***" shall have the meaning set forth in Section 8.5(a).

"*Prosecute*" means to prepare, file and prosecute any and all applications for Patent Rights (and including any proceedings relating to such prosecution, including reissues, reexaminations, protests, interferences, oppositions, post-grant reviews or similar proceedings and requests for patent extensions, and all foreign equivalents of any of the foregoing). The term **"*Prosecution*"** shall have the corresponding meaning.

"***Protocol***" means the clinical trial protocol, for any Combined Therapy Clinical Trial to be conducted by Olema under this Agreement, prepared by Olema as provided in this Agreement, and as such protocol may be amended, updated or modified by Olema from time to time in accordance with this Agreement.

"***Publication Dispute***" shall have the meaning set forth in Section 8.4(b).

"***Quarter***" means a calendar quarter.

"***Regulatory Authority***" means the FDA or any governmental authority outside the United States (whether supranational, national, federal, provincial and/or local) that is the counterpart to the FDA, including the European Medicines Agency for the European Union.

"***Regulatory Documentation***" means, with respect to a Party's Single Agent Compound, all submissions to Regulatory Authorities in connection with the development (including seeking regulatory approval or registration) of such Single Agent Compound, as applicable, including all INDs and amendments thereto, IBs, NDAs and amendments thereto, drug master files, correspondence with regulatory agencies, periodic safety update reports, adverse event files, complaint files, inspection reports and manufacturing records, in each case together with all supporting documents (including documents that include clinical data).

"***Results***" shall have the meaning set forth in Section 8.4(b).

"***Right of Cross-Reference***" means, with regard to a Party, a grant of rights (including to or through another party) that allows the applicable Regulatory Authority in a country to have access to relevant information (by cross-reference, incorporation by reference or otherwise) contained in Regulatory Documentation (and any data contained therein) filed with such Regulatory Authority by or on behalf of the other Party (or its Affiliate) with respect to the other Party's Single Agent Compound (and, in the case of Novartis, the Right of Cross-Reference to the Combined Therapy Clinical Trial IND), only to the extent reasonably needed for the conduct of the Combined Therapy Clinical Trials in such country or as otherwise expressly permitted or required under this Agreement to enable a Party to exercise its rights or perform its obligations hereunder, and, except as to information contained in the Combined Therapy Clinical Trial IND pertaining to the Combined Therapy, without the disclosure of such information to such Party.

"***Safety Issue***" means any information suggesting an emerging safety concern or possible change in the risk-benefit balance for the Novartis Study Drugs or Olema Study Drug, including information on a possible causal relationship between an Adverse Event and a drug, the relationship being unknown or incompletely documented previously.

"***Safety Signal***" means information arising from one or multiple sources, including observations and experiments, which suggests a new potentially causal association, or a new aspect of a known association between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action.

"***Sample***" means a biological specimen collected under the Combined Therapy Clinical Trials from a study subject in such trial (including fresh and/or archived tumor samples, serum, peripheral blood mononuclear cells, plasma, and whole blood for RNA and DNA sample isolation).

"***Shortage***" shall have meaning set forth in Section 4.5.

"***Single Agent Compound***" or "***Compound***" means: (a) with respect to Olema, the Olema Study Drug, as monotherapy, and (b) with respect to Novartis, the Novartis Study Drugs, as monotherapy.

"***Sponsor***" means an applicant or holder of clinical studies applications/notifications.

"***Study Data***" means: (a) the actual raw results, records and data of the Combined Therapy Clinical Trials, including the case report forms (CRFs) for such study and all raw data as recorded in such CRFs; (b) all information relating to adverse events resulting from the Combined Therapy Clinical Trials, including all reports of Adverse Events, Serious Adverse Events, and Serious Adverse Drug Reactions; (c) all analyses of the raw results of the Combined Therapy Clinical Trials conducted using the statistical analysis plan and any bioanalysis plan pursuant to or set forth in the applicable Protocol (or as otherwise agreed to by the Parties); and (d) the Final Study Report, the periodic reports (e.g. quarterly), and all other reports of the results of the Combined Therapy Clinical Trials or the analyses of such results prepared under this Agreement in accordance with the applicable Protocol prior to the completion of the Final Study Report.

"***Study Invention***" means any Technology, whether or not patentable, that is made, conceived, or first actually reduced to practice by, for or on behalf of a Party, or by, for or on behalf of the Parties together, including by or with a Third Party in the performance of the Combined Therapy Clinical Trials, pursuant to, in relation to, or in connection with the conduct of the Combined Therapy Clinical Trials (including the analysis of the Study Data in connection with preparing the final study report for such trial, *but excluding* in each case all Study Data).

"***Sunshine Laws***" shall have the meaning set forth in Section 8.5(c).

"***Quality Documentation***" shall have the meaning set forth in Section 4.3.

"***Technology***" means know-how, inventions, discoveries, trade secrets, knowledge, technology, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, specifications, data and results not generally known to the public (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and know-how, including study designs and protocols), and all other information, in all cases, whether or not patentable, in written, electronic or any other form now known or hereafter developed, and materials, including Regulatory Documentation.

"***Term***" shall have the meaning set forth in Section 11.1.

"***Territory***" means all countries and territories in the world.

"***Third Party***" means any Person or entity other than Olema and Novartis and their respective Affiliates.

"***Third Party Claim***" shall have the meaning set forth in Section 10.1.

"***Third Party License Payments***" means any payments (e.g., upfront payments, milestones, royalties) due to any Third Party under license agreements or other written agreements granting rights to intellectual property owned or controlled by such Third Party to the extent that such rights are necessary for (a) the making, using or importing of a Party's Single Agent Compound for the conduct of the Combined Therapy Clinical Trials, or (b) the conduct of the Combined Therapy Clinical Trials.

"***Trial Site***" means a clinical site selected by Olema upon written notice to Novartis at which a Combined Therapy Clinical Trial is conducted on study subjects in such trial.

ARTICLE 2

SCOPE

2.1 Scope.

(a) Olema and Novartis will collaborate with respect to the conduct of certain activities relating to the Combined Therapy Clinical Trials as outlined in the Development Plan in Appendix A. Olema will be responsible for using Commercially Reasonable Efforts to conduct the Combined Therapy Clinical Trials in accordance with the Development Plan, the applicable Protocol, all Applicable Law, and the terms of this Agreement. The Parties agree to the Protocol Synopsis set forth in Appendix D. Olema shall be responsible for creating the first draft of each Protocol and provide it to Novartis for review and comment. To the extent any changes need to be made to a Protocol, Olema will have the final decision regarding the contents of the Protocol; *provided that*: (i) Olema will notify Novartis of any proposed amendments to the applicable Protocol (including any amendments to any final Protocol initially approved by an IRB) and Olema will consider any comments provided by Novartis regarding the proposed amendments (it being understood that the Parties will endeavor to set forth in writing the circumstances (e.g., administrative matters) where Olema may make specific Protocol amendments without the need for Novartis to review and comment), and (ii) any changes to the applicable Protocol that pertain to the administration of the Novartis Study Drugs must be reviewed and expressly approved by Novartis in writing (such approval not to be unreasonably withheld) or the change may not be implemented. Novartis shall have [***] from the date on which Olema provides the applicable Protocol amendment to Novartis to provide any comments to Olema concerning the proposed amendment, and, as to changes covered by subsection (ii) above, to approve or reject approval of such proposed change (and if such change is not expressly disapproved by Novartis within such period, such change shall be deemed approved).

(b) The Parties shall discuss the Development Plan and the conduct of the Combined Therapy Clinical Trials from time to time and shall discuss and approve amendments to the Development Plan as appropriate. Any such amendments shall be in writing, and shall be effective upon execution of such written amendments by the authorized senior officer of each Party.

(c) Olema will be the Sponsor of record for an IND which includes any Combined Therapy Clinical Trials (the "***Combined Therapy Clinical Trial IND***"). Olema will be the regulatory sponsor of the Combined Therapy Clinical Trials and the sole holder of all legal interests in the Combined Therapy Clinical Trial IND; *provided, however, that* Olema hereby grants Novartis the Right of Cross-Reference for the Combined Therapy Clinical Trial IND. Upon the specific written request of Novartis, at Novartis' expense, Olema agrees to promptly file appropriate letters and other documentation with the FDA enabling Novartis to reference the Combined Therapy Clinical Trial IND in connection with Novartis clinical development activities. Upon the specific written request of Novartis, at Novartis' expense, Olema agrees to promptly file appropriate filings with any applicable Regulatory Authorities outside of the US for the purpose of enabling Novartis to reference the Combined Therapy Clinical Trial IND in connection with Novartis clinical development activities. Olema may not grant any Third Party any Right of Cross-Reference with respect to any portion of the Combined Therapy Clinical Trial IND pertaining to Novartis's Study Drug for use as monotherapy or for use in combination with any molecules, agents, antibodies or compounds other than with Olema Study Drug. Olema will prepare a template patient informed consent form for the Combined Therapy Clinical Trials in consultation with Novartis (it being understood that the portion of the informed consent form relating to the Novartis Study Drugs will be provided by Novartis) to provide to Study Sites. Such form shall contain provisions permitting sharing of any Study data among the Parties and their Affiliates in accordance with HIPAA, the EU General Data Protection Regulation 2016/679 or any other similar Applicable Law. Any material changes to such informed consent form proposed by Olema, a Trial Site, a Regulatory Authority, or other Third Party that relate to the Novartis Study Drugs will be subject to Novartis' written consent, not to be unreasonably withheld; provided, however, that Novartis shall review such proposed changes to such informed consent form and communicate to Olema Novartis' suggested changes to such form within [***] after receipt thereof from Olema, failing which

Olema's proposed changes to such informed consent form shall be deemed accepted by Novartis. Olema will be solely responsible for conducting the Combined Therapy Clinical Trials, using its Commercially Reasonable Efforts, contracting with Study Sites, and creating a report at the conclusion of the trial (the "***Final Study Report***"), unless otherwise agreed to by the Parties in writing.

(d) Novartis will provide all relevant safety data and information for the Novartis Study Drugs in the Territory available to Olema, including pursuant to a separate pharmacovigilance agreement in accordance with the terms of Section 2.3 and will provide Olema any updates thereto at the same time as the same are available. Olema shall, and shall require that each applicable Trial Site for the Combined Therapy Clinical Trials shall, use any such data provided pursuant to this Section 2.1(d) solely (A) to evaluate the safety and efficacy of the Combined Therapy for use in Combined Therapy Clinical Trials, (B) to meet any regulatory requirements pertaining to the conduct of the Combined Therapy Clinical Trials, and (C) to enable Olema to draft and update as necessary the investigator's brochure for the Combined Therapy Clinical Trials. Olema will ensure that the applicable Trial Sites for the Combined Therapy Clinical Trials are obligated to protect such information and disclosures as set forth in Article 8. Olema's right to use the information provided by Novartis shall remain in effect through the completion of all activities under the Development Plan and otherwise for purposes of complying with legal and regulatory requirements with respect thereto.

(e) If reasonably required for the conduct of the Combined Therapy Clinical Trials and requested in writing by Olema, Novartis shall provide Rights of Cross-Reference to its existing Regulatory Documentation for the Novartis Study Drugs for those countries in the Territory where the Combined Therapy Clinical Trials will be conducted solely as reasonably needed to allow the Combined Therapy Clinical Trials to be conducted under the Combined Therapy Clinical Trial IND in each applicable country; *provided that* such Right of Cross-Reference shall terminate upon the expiration or termination of this Agreement and shall not be used for purposes of conducting any other clinical studies, except (a) as set forth in Section 3.1(b) and Section 8.3, and (b) that, in the case of termination for a Material Safety Issue pursuant to Section 11.4, such Rights of Cross-Reference shall remain in effect solely (i) to the extent necessary to permit Olema to comply with any outstanding obligations required by a Regulatory Authority and/or Applicable Law or (ii) as necessary to permit Olema to continue to dose subjects enrolled in the Combined Therapy Clinical Trials through completion of the applicable Protocol if required by the applicable Regulatory Authority(ies) and/or Applicable Laws.

(f) Other than as may be agreed to by the Parties, this Agreement does not create any obligation on the part of Novartis to provide the Novartis Study Drugs for any activities other than the Combined Therapy Clinical Trials, nor does it create any obligation on the part of Olema to provide the Olema Study Drug for any activities other than the Combined Therapy Clinical Trials. Nothing in this Agreement will (i) prohibit either Party from performing clinical studies other than the Combined Therapy Clinical Trials relating to its respective Study Drug, either individually or in combination with any other compound or product, in any therapeutic area, or (ii) create an exclusive relationship between the Parties with respect to either Compound.

2.2 Combined Therapy Clinical Trials

(a) During the Term, Olema shall manage, direct and oversee the conduct of the Combined Therapy Clinical Trials. To that end, the Parties shall:

(i) monitor the progress of the conduct of the Combined Therapy Clinical Trials and review the enrollment and results, and conduct their tasks under the Development Plan, as appropriate, including;

(ii) review and approve any changes to the Development Plan, and discuss and prepare (for the Parties' approval) written amendments or modifications to the Development Plan, as appropriate, based on the trial progress and results;

(iii) serve as a forum for each Party to share information and data relating to such Party's Study Drug with the other Party to the extent that such information and data relates to the safety profile of such Party's Study Drug, or to the extent that such information and data is reasonably required to inform the Development Plan for the Combined Therapy; and

(iv) discuss and attempt to resolve any issues arising in the conduct of the Combined Therapy Clinical Trials or in connection with the collaboration hereunder, as presented to it by either of the Parties.

(b) Decisions that relate solely to a Party's Study Drug will be made solely by such Party.

(c) Decisions that relate solely to the Novartis Alpelisib Metabolite will be made solely by Novartis.

2.3 Adverse Event Reporting.

Olema, as the Sponsor, will be solely responsible for compliance with all Applicable Law pertaining to safety reporting for the Combined Therapy Clinical Trials and related activities. The Parties will execute a pharmacovigilance agreement promptly following the Effective Date to ensure the exchange of relevant safety data within appropriate timeframes and in appropriate format to enable the Parties to fulfill local and international regulatory reporting obligations and to facilitate appropriate safety reviews. The pharmacovigilance agreement will include safety data exchange procedures governing the coordination of collection, investigation, reporting, and exchange of information concerning any adverse experiences, pregnancy reports, and any other safety information arising from or related to the use of the Novartis Study Drugs and the Olema Study Drug in the Combined Therapy Clinical Trials, consistent with Applicable Law and in accordance with the terms of the pharmacovigilance agreement. Such guidelines and procedures shall be in accordance with, and sufficient to enable the Parties and their Affiliates to fulfill, local and international regulatory reporting obligations to, Regulatory Authorities.

2.4 Clinical Study Designated Contact. Each Party will designate an employee within its organization (the "***Designated Clinical Contact***") who will coordinate and/or facilitate:

(a) the review of Protocol amendments submitted by Olema for Novartis approval and with whom comments thereon may be discussed;

(b) any Novartis clinical and regulatory responsibilities and communications regarding the Combined Therapy Clinical Trials;

(c) internal Novartis review of any document or regulatory communication and the provision of any Novartis comments; and

(d) discussion of any other topics, results, or issues relating to the Combined Therapy Clinical Trials requested by Olema or Novartis;

2.5 Conduct. Each Party shall use Commercially Reasonable Efforts to (a) perform and fulfill its respective activities and obligations under the Combined Therapy Clinical Trials and this Agreement on a timely basis and in an effective manner consistent with prevailing standards, (b) supply the quantities of its Compound in accordance with Article 4 as needed to conduct the Combined Therapy Clinical Trials on a timely basis, and, in the case of Olema, package and deliver same to study sites on a timely basis, and (c) in the case of Olema, conduct and complete the Combined Therapy Clinical Trials on a timely basis in accordance with the applicable Protocol and Third Party agreements relating thereto, and provide sufficient resources, funding and personnel to conduct and perform the Combined Therapy Clinical Trials on a timely basis in accordance with the applicable Protocol for same and the terms of this Agreement. Each Party

shall perform its duties and obligations in relation to the Combined Therapy Clinical Trials in accordance with Applicable Law, including GCP, GLP and GMP as applicable.

ARTICLE 3

LICENSE GRANTS

3.1 Grants by Novartis. Novartis hereby grants, and shall cause its Affiliates to grant (effective as of the Effective Date), to Olema and Olema's Affiliates a non-exclusive, non-transferable, royalty-free license (with the right to sublicense solely pursuant to the terms of and subject to the limitations of Section 3.3) under the Novartis Background Patent Rights, Novartis Background Technology and Novartis Regulatory Documentation to use the Novartis Study Drugs in research and development, in the Territory, solely to the extent reasonably needed to conduct the Combined Therapy Clinical Trials, subject to and in accordance with the terms and conditions of this Agreement. The rights granted under this Section 3.1 include Rights of Cross-Reference to the relevant Novartis Regulatory Documentation to the extent reasonably needed for conducting the activities assigned to Olema in the Development Plan and for conducting the Combined Therapy Clinical Trials (which Rights of Cross-Reference shall survive any expiration or termination of this Agreement with respect thereto). With respect to such Rights of Cross-Reference, Novartis shall reasonably assist and cooperate with Olema to effect such Rights of Cross-Reference, including by making written authorizations and other filings with the applicable Regulatory Authority as reasonably needed to effect or implement such Rights of Cross-Reference.

3.2 Grants by Olema. Olema hereby grants, and shall cause its Affiliates to grant (effective as of the Effective Date), to Novartis and Novartis' Affiliates a non-exclusive, non-transferable, royalty-free license (with the right to sublicense solely pursuant to the terms of and subject to the limitations of Section 3.3), under Olema Background Patent Rights, Olema Background Technology and Olema Regulatory Documentation to use Olema Study Drug in research and development, in the Territory, solely to the extent reasonably needed for Novartis to conduct its specified activities under the Development Plan for the Combined Therapy Clinical Trials and subject to and in accordance with the terms and conditions of this Agreement. The rights granted under this Section 3.2 include Rights of Cross-Reference to the relevant Olema Regulatory Documentation solely to the extent reasonably needed for conducting the activities assigned to Novartis in the Development Plan. With respect to such Rights of Cross-Reference, Olema shall reasonably assist and cooperate with Novartis to effect such Rights of Cross-Reference, including by making written authorizations and other filings with the applicable Regulatory Authority as reasonably needed to effect or implement such Rights of Cross-Reference.

3.3 Sublicensing.

(a) (i) Either Party shall have the right to grant sublicenses under the licenses granted to it under Sections 3.1 and 3.2 (as applicable), to Affiliates and to Third Parties (including Trial Sites), if reasonably needed for such Party to perform its duties with respect to the conduct of the Development Plan and Combined Therapy Clinical Trials, solely as reasonably needed to assist Olema in carrying out its responsibilities with respect to the Combined Therapy Clinical Trials, and (ii) excluding all Novartis Study Inventions and Novartis Study Patent Rights pertaining to the Novartis Alpelisib Metabolite, Olema shall have the right to grant sublicenses to Trial Sites under the Novartis Study Inventions and Novartis Study Patent Rights for non-commercial, internal research and teaching purposes and for patient care purposes.

(b) With regard to any sublicenses made under this Agreement as permitted hereunder, (i) the sublicensees, except Affiliates (so long as they remain Affiliates), shall be subject to written agreements that bind such sublicensees to obligations that are consistent with such Party's applicable obligations under this Agreement including confidentiality and non-use provisions no less restrictive than those set forth in herein, and provisions regarding intellectual property that ensure that the Parties will have the rights provided under this Agreement to any intellectual property relating to their Single Agent Compound and/or the Novartis Alpelisib Metabolite and/or the Combined Therapy created by such

sublicensee, (ii) such Party shall provide written notice to the other Party of any such sublicense; and (c) the each Party shall remain liable to the other Party for all actions of its sublicensees.

3.4 No Implied Licenses. Except for the rights as specifically and expressly granted and set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, in any intellectual property of the other Party, including Confidential Information disclosed to it under this Agreement or under any Patent Rights Controlled by the other Party or its Affiliates.

ARTICLE 4

MANUFACTURE AND SUPPLY

4.1 Olema Study Drug Manufacture and Supply.

(a) Olema shall be responsible, [***], for manufacturing, packaging and labeling (or having manufactured, packaged or labeled) GMP-grade quantities of Olema Study Drug, as well as obtaining any other drug (other than the Novartis Study Drugs provided by Novartis pursuant to Section 4.2) required for the conduct of the Combined Therapy Clinical Trials, and shall package and label if and as required by the applicable Protocol and/or applicable Regulatory Authorities all drugs (except with respect to the Novartis Study Drugs, as further described in Section 4.2(a) below) used in the Combined Therapy Clinical Trials, on a timely basis and in accordance with applicable specifications as required for the conduct of the Combined Therapy Clinical Trials. Olema Study Drug shall be manufactured in accordance with Applicable Law (including GMP) and shall be of similar quality to Olema Study Drug used by Olema for its other clinical trials of Olema Study Drug.

(b) Olema shall provide Novartis with prompt notice of any Manufacturing and supply issues with respect to Olema Study Drug or Novartis Study Drugs of which it becomes aware that may adversely impact the conduct or timelines of the Combined Therapy Clinical Trials.

(c) For Section 4.1 of this Agreement, the term "Olema Study Drug" shall mean Olema's proprietary OP-1250 compound, including salts thereof, and any drug candidate or product containing such compound.

4.2 Novartis Study Drugs.

(a) Manufacture and Supply. Novartis shall Manufacture or have Manufactured the Novartis Study Drugs in such quantities as reasonably needed, and at the points in time as needed to meet the timelines in the applicable Protocol in accordance with the Development Plan, for the Combined Therapy Clinical Trials, and shall supply such Novartis Study Drugs to Olema or its designee for use solely in the Combined Therapy Clinical Trials. Novartis will, [***], deliver the Novartis Study Drugs in accordance with the terms of the Supply Agreement to the Olema-designated location in the United States for use in the applicable Combined Therapy Clinical Trial, and otherwise subject to and in accordance with the additional delivery information, and qualitative and quantitative criteria specified in the Quality Documentation. [***] All costs associated with the subsequent transportation, warehousing and distribution of Novartis Study Drugs will be borne by [***]. [***] shall be responsible for the payment of any Third Party License Payments that may be due based on the manufacture, supply and use of the Novartis Study Drugs used in the Combined Therapy Clinical Trials. The Novartis Study Drugs shall be manufactured in accordance with Applicable Law (including GMP) and shall be of similar quality to the Novartis Study Drugs used by Novartis for its other clinical trials of the Novartis Study Drugs. Pursuant to the Quality Documentation, Novartis shall be responsible for the regulatory compliance of the quality of the Novartis Study Drugs at the time the Novartis Study Drugs is Delivered to Olema. Upon Delivery of Novartis Study Drugs to Olema, and with respect to the Novartis Study Drugs, Olema agrees to (i) obtain all required licenses, certificates and permits in connection with the subsequent transportation and storage thereof; (ii) comply with all Regulatory Approvals, including all approvals and licenses, or other requirements

pertaining to Novartis Study Drugs; (iii) to maintain the necessary records to comply with all Regulatory Approvals and other Applicable Laws; (iv) to not re-export the Novartis Study Drugs except as authorized in writing by Novartis and in compliance with Applicable Laws; and (v) not to sell, transfer or dispose of Novartis Study Drugs in violation of the export laws of the country from which the Novartis Study Drugs is shipped. Olema will be responsible for providing Novartis with any information reasonably necessary in order to enable Novartis to fulfill any shipment of Novartis Study Drugs and to comply with all labeling and other applicable legal requirements in the countries in which the Combined Therapy Clinical Trials will be conducted. [***] will pay all taxes, import duties, sales, use or privilege taxes, value-added taxes, excise or similar taxes or duties levied upon either Party or any Affiliate thereof by any jurisdiction, political subdivision or agency for the supply of Novartis Study Drugs after Delivery thereof to Olema under this Agreement. Novartis will be responsible for obtaining all required documents and approvals in order for Novartis Study Drugs to clear customs in applicable countries necessary for Delivery of Novartis Study Drugs to Olema hereunder. Olema will be responsible for obtaining all required documents and approvals in order for Novartis Study Drugs to clear customs in applicable countries in which Novartis Study Drugs will be used after Delivery thereof to Olema; provided, however, that upon Olema's request, Novartis shall reasonably cooperate and provide Olema with any information necessary to assist Olema in obtaining such customs clearance, [***]. Subject to Section 4.6, the Parties shall cooperate in accordance with Applicable Law to minimize indirect taxes (such as value added tax, sales tax, consumption tax and other similar taxes) relating to supply or use of the Novartis Study Drugs in connection with this Agreement.

(b) Use of Novartis Study Drugs Supplied by Novartis to Olema. Olema shall use the quantities of Novartis Study Drugs supplied to it under this Agreement solely as reasonably needed for, and in accordance with, this Agreement and the applicable Protocol, and for no other purpose, including as a reagent or tool to facilitate its internal research efforts, for any commercial (i.e., non-clinical) purpose, or for other clinical or non-clinical research unrelated to the Combined Therapy Clinical Trials. Except as may be required or expressly permitted by the applicable Protocol or the Quality Documentation, Olema shall not perform, and shall not allow any Third Party to perform, any analytical testing of the quantities of Novartis Study Drugs supplied to it under this Agreement. If Study Drug supplied by Novartis is (after delivery by Novartis) lost, damaged, destroyed or becomes (due to fault other than Novartis) unable to comply with applicable specifications while under the control of Olema or any of its (sub)contractors, including common carriers and clinical study sites contracted by Olema, [***]. If Novartis Study Drugs supplied by Novartis is, at the time of delivery to Olema or its designee, non-conforming with the warranty in Section 9.12, or after delivery becomes non-conforming due to fault of Novartis, then [***].

(c) Novartis shall provide Olema with prompt notice of any Manufacturing and supply issues with respect to Novartis Study Drugs of which it becomes aware that may adversely impact the conduct or timelines of the Combined Therapy Clinical Trials

4.3 Quality Documentation. Novartis shall supply the Novartis Study Drugs to Olema or its designee in accordance with the terms of: (i) a separate supply agreement ("**Supply Agreement"**) governing forecasting, ordering, procedures for acceptance and rejection, and other customary provisions for the supply of the Novartis Study Drugs for the Combined Therapy Clinical Trials, and (ii) a separate quality agreement (**"Quality Agreement"**) outlining the additional roles and responsibilities relative to the quality of the Novartis Study Drugs in support of the Combined Therapy Clinical Trials (the Supply Agreement and Quality Agreement collectively referred to herein as "***Quality Documentation***"). The Parties shall finalize and execute the Quality Documentation before the date on which the first shipment of the Novartis Study Drugs is supplied for use in the Combined Therapy Clinical Trials. The Quality Documentation shall include the responsibility for quality elements as well as exchanged GMP documents and certifications required to release the Novartis Study Drugs for the Combined Therapy Clinical Trials. In addition, the Quality Documentation shall detail the documentation required for each shipment of Novartis Study Drugs supplied to Olema or its designee for use in the Combined Therapy Clinical Trials.

4.4 Supply Forecast. Estimated supply and delivery details will be outlined in the Development Plan and will be updated by the Parties by mutual agreement (which agreement can be

effected by the Parties' Designated Supply Contacts and without need for an amendment to this Agreement) based on the actual trial enrollment. Olema will promptly inform Novartis of any change in its requirements for Novartis Study Drugs, and Novartis will [***].

4.5 Shortages. In the event of a supply interruption or shortage of Novartis Study Drugs as determined by Novartis pursuant to its internal processes and policies (a "***Shortage***"), such that Novartis reasonably believes that it will not be able to fulfill its supply obligations under this Agreement, Novartis will provide prompt written notice thereof to Olema (including the quantity of Novartis Study Drugs that Novartis reasonably estimates it will be able to supply) and, upon request, the Parties will promptly discuss such situation (including how the quantities of Novartis Study Drugs that Novartis is able to supply under this Agreement will be allocated within the Combined Therapy Clinical Trials). Notwithstanding anything to the contrary contained herein, in the event of a Shortage of the Novartis Study Drugs, [***]; provided, however, that [***] shall (i) [***], and (ii) [***].

4.6 Participating Countries; Customs Valuation. Olema will provide Novartis in writing with a list of each country in which it proposes to conduct the Combined Therapy Clinical Trials prior to execution of any site agreement or CRO agreement for that country pertaining to a Combined Therapy Clinical Trial. During the conduct of the Combined Therapy Clinical Trials, Olema will send in writing any changes to the list of participating countries to Novartis [***]. If no changes are sent to Novartis by Olema for a particular [***], the prior [***] participating country list will be used as the basis for customs valuation for that [***]. Novartis will provide Olema with country-specific customs valuations initially for the Novartis Study Drugs prior to initiation of the Combined Therapy Clinical Trials and at the end of each [***] during the conduct of the Combined Therapy Clinical Trials. Olema will use the Novartis provided values for the import/export process in the listed participating countries and not make any change to such valuations without Novartis's prior written consent.

4.7 Designated Supply Contact. Each Party will designate an individual (the "***Designated Supply Contact***") that a Party may contact to assist with coordinating supplies and facilitating the resolution of any issues or concerns arising in connection with the supply of the Novartis Study Drugs for use in the Combined Therapy Clinical Trials, except as required by Applicable Law.

ARTICLE 5

RESPONSIBILITIES

5.1 Specific Responsibilities of Olema. Olema shall, subject to the terms of the applicable Protocol, applicable terms and conditions of the Development Plan and this Agreement, and any other written agreement between the Parties relating to the Combined Therapy Clinical Trials, manage and be responsible for the conduct of the Combined Therapy Clinical Trials, including timelines and contingency planning. particular, and not in limitation of the foregoing, Olema shall use Commercially Reasonable Efforts to perform (itself and/or through Third Parties, including Trial Sites, CROs and investigators) and/or be responsible for the following (items (a) to (p) below, collectively the "***Operational Matters***") with respect to the Combined Therapy Clinical Trials:

(a) compiling, amending and filing all necessary Combined Therapy Clinical Trials Regulatory Documentation with Regulatory Authority(ies), maintaining and acting as the sponsor of record as provided in 21 CFR 312.50 (and applicable comparable ex-US laws) with responsibility, unless otherwise delegated in accordance with 21 CFR 312.52 (and applicable comparable ex-US laws), for the Combined Therapy Clinical Trials and making all required submissions to Regulatory Authorities related thereto on a timely basis;

(b) conducting clinical study start-up activities, communicating with and obtaining approval from IRBs for the applicable Protocol and other relevant documents, and clinical study subject recruitment and retention activities, all for the Combined Therapy Clinical Trials;

(c) listing of the Combined Therapy Clinical Trials, if it is required to be listed on a public database, on www.clinicaltrials.gov or other applicable public registry in any country in which such Combined Therapy Clinical Trials is being conducted, all in accordance with Applicable Law and in accordance with Olema's internal policies relating to clinical trial registration;

(d) providing Novartis with reasonable advance notice of meetings or other non-written communications with a Regulatory Authority regarding the Combined Therapy Clinical Trials, and the opportunity to participate in each such meeting or other non-written communication to the extent such meeting or communication involves a safety, efficacy or toxicology issue relating to the Combined Therapy or the Novartis Study Drugs or the Novartis Alpelisib Metabolite or any other matter that likely could have an adverse effect on the Novartis Study Drugs. In such case that Olema intends to provide such a communication that relates to the Novartis Study Drugs or the Novartis Alpelisib Metabolite, Olema will provide Novartis with the opportunity to review and provide comments to Olema within [***] receipt thereof from Olema, and, if materially inconsistent with the applicable Protocol, approve such submissions and written correspondence with a Regulatory Authority to the extent that it relates to the Novartis Study Drugs or the Novartis Alpelisib Metabolite;

(e) provide Novartis (i) a written summary of meetings or other non-written communications with a Regulatory Authority within [***] of such meeting or communication, and (ii) copies of any official correspondence to or from a Regulatory Authority within [***] receipt or provision, in each case of (i) or (ii) to the extent involving a safety, efficacy or toxicology issue relating to the Combined Therapy or the Novartis Study Drugs or the Novartis Alpelisib Metabolite or any other matter that likely could have an adverse effect on the Novartis Study Drugs, and copies of all material Combined Therapy Clinical Trials Regulatory Documentation and correspondence that relates to same within [***] of submission to Regulatory Authorities;

(f) subject to the terms of this Agreement, the selection and payment of, negotiation of the terms of, contracting with, managing and overseeing compliance of its agreement by and the receipt of contract deliverables from, any CRO or vendor selected by Olema to assist in the performance of the Combined Therapy Clinical Trials. Olema shall have the responsibility to determine and approve contract deliverables that adhere to the terms of this Agreement and manage contract performance, including executing Trial Site contracts, drafting and obtaining IRB approval for Trial Site informed consent forms (each an "***ICF***"), obtaining signed ICFs, and monitoring clinical plans. Olema will be responsible for ensuring that, to its knowledge, the terms of all such contracts and ICFs: (i) do not conflict with the terms of this Agreement, (ii) allow Olema to provide Novartis with access to and use of Study Data, Samples, and other applicable information and documents resulting from the Combined Therapy Clinical Trials as required pursuant to this Agreement (and in no event less than the same use rights thereto granted to Olema), (iii) do not by their express terms adversely affect the Novartis Background Technology or Novartis Background Patent Rights (or the enforcement or defense thereof), the Combined Therapy, or the Novartis Study Drugs as monotherapy, (iv) do not impose a new obligation, whether direct, indirect, or contingent, upon Novartis that is not set forth in this Agreement, (v) retain each of the Parties' respective intellectual property rights in Olema Study Drug, Novartis Study Drugs, the Novartis Alpelisib Metabolite and Combined Therapy consistent with this Agreement, and (vi) comply with Applicable Law;

(g) providing Novartis (if previously prepared by Olema and if requested by Novartis) with copies of the draft and final global site templates of the applicable Combined Therapy Clinical Trial's ICF. Olema shall ensure that each ICF does not impose any financial obligation, liability, damages or other cost upon Novartis with respect to any injury (including death) suffered by a Combined Therapy Clinical Trial subject whether or not resulting from the administration of the Novartis Study Drugs or direct a study subject to Novartis to seek reimbursement for any costs or seek compensation for any injury incurred in connection with the Combined Therapy Clinical Trials;

(h) if requested by Novartis, providing Novartis within [***] with minutes from any and all external drug safety monitoring boards for the Combined Therapy Clinical Trials after receipt by

Olema, to the extent relating to the Novartis Study Drugs, the Novartis Alpelisib Metabolite, or the Combined Therapy;

(i) Informing and updating Novartis on a [***] basis (with significant issues to be communicated promptly after Olema becomes aware of same) regarding a reasonable summary of all Operational Matters, so that if Novartis has any significant concerns or material disagreements regarding same, the matter can be discussed with Olema. It is expected that at least [***] during the Term shall be in person at an Olema facility (or as otherwise agreed). The other [***] meetings [***] need not be in person and may be by telephone or any other method determined by the Parties. Each Party will bear its own costs associated with attending such meetings. Without limiting the foregoing, Olema shall inform Novartis on a [***] basis as to the overall Combined Therapy Clinical Trials progress -- [***], and any other Combined Therapy Clinical Trials-related matters reasonably requested by Novartis to the extent involving a safety, efficacy or toxicology issue relating to the Combined Therapy or the Novartis Study Drugs or the Novartis Alpelisib Metabolite or any other matter that likely could have an adverse effect on the Novartis Study Drugs;

(j) owning and being responsible for (or appointing a Third Party to be responsible for) the maintenance of the Global Safety Database and being responsible for safety reporting, collecting, evaluating and reporting Serious Adverse Events, other safety data and any further pharmacovigilance information from the Combined Therapy Clinical Trials;

(k) analyzing the Study Data in a timely fashion and providing Novartis with access to the Study Data after Olema is in possession thereof, as follows:

(i) top line data and a copy of all Clinical Study Reports (CSRs) for the Combined Therapy Clinical Trials, in each case, as and promptly after being received by Olema's clinical management;

(ii) if requested by Novartis, sharing with Novartis for review and comment clinical summaries and/or final clinical trial report (and/or statistical analysis in accordance with the applicable Protocol) from the applicable Combined Therapy Clinical Trial;

(iii) if requested by Novartis, within [***], access to those safety databases that will be used for any interim review by an external consultant (or drug safety monitoring board, if required) for the applicable Combined Therapy Clinical Trial;

(iv) if requested by Novartis, [***], access to case report forms or patient profiles for all patients in the applicable Combined Therapy Clinical Trial;

(v) if requested by Novartis, within [***], an electronic copy of the clean database (the form and format of the clean database to be reasonably acceptable to both Parties);

(vi) if requested by Novartis, subject to any third party requirements, providing Novartis with any programs or SAS codes to be used for any statistical analysis plan for the Combined Therapy Clinical Trials; and

(vii) (A) safety analyses, (B) new and/or changing Safety Signals and Safety Issues, (C) new and/or changing toxicology and efficacy signals, and (D) any statistical analysis, immunogenicity analysis, or bioanalysis, in each case relating to the Novartis Study Drugs, the Novartis Alpelisib Metabolite, Olema Study Drug and/or the Combined Therapy, arising from or in connection with the conduct of the Combined Therapy Clinical Trials, as and when the same are received by Olema;

(l) obtaining supplies of any co-medications, to the extent any such co-medications are required for use in the Combined Therapy Clinical Trials, and providing to Novartis any information

related to the Combined Therapy Clinical Trials that is provided to the manufacturer of any co-medication within [***];

(m) if requested by Novartis, providing information regarding the pharmacokinetics, efficacy and safety of Olema Study Drug in combination with the Novartis Study Drugs in the Combined Therapy Clinical Trials;

(n) performing either directly or through third parties collection of Samples required by the applicable Protocol;

(o) handling and addressing inquiries from the Combined Therapy Clinical Trials subjects and investigators; and

(p) such other responsibilities as may be agreed to in writing by the Parties.

5.2 Novartis Operational Responsibilities. Novartis shall be responsible for the following activities:

(a) Manufacturing and supplying GMP-grade quantities of the Novartis Study Drugs, as further described in Article 4 above, subject to and in accordance with the Development Plan and applicable Protocol, and, where and to the extent provided in the Quality Documentation, providing GMP information and documentation that is reasonably needed by Olema Qualified Person (as such term will be defined in the Quality Documentation) to release Novartis Study Drugs for the Combined Therapy Clinical Trials;

(b) where and to the extent provided in the Quality Documentation, providing for the release by a Novartis Qualified Person or providing the necessary documentation in support of such quality release, of the Novartis Study Drugs if such release is required for the Combined Therapy Clinical Trials;

(c) to the extent reasonably needed for the conduct of the Combined Therapy Clinical Trials, providing a Right of Cross-Reference to the relevant Regulatory Documentation for the Novartis Study Drugs as set forth in Section 2.1(c) and (e), and Section 3.1;

(d) conducting such study-related activities as are assigned to Novartis in the Development Plan and for collaborating with Olema in such study activities; and

(e) such other responsibilities as may be agreed to in writing by the Parties.

5.3 Development Costs. Expenses incurred as described in Sections 4.1 and 4.2 (regarding manufacture and supply) and Article 6 (regarding intellectual property) shall be borne or shared by the Parties as provided in such respective Articles. Novartis will reimburse Olema for Direct Outside Costs it incurs related to conducting the activities under the Development Plan in conducting the Combined Therapy Clinical Trials. Novartis shall make a total payment of not to exceed USD$[***] USD) as set forth in the Budget. All payments shall be made against invoices, which will be issued by Olema in the form set forth in Appendix C (an "Invoice"). Within [***] after the end of each Quarter during the Term, Olema will prepare a detailed accounting of the total Direct Costs incurred during such Quarter and shall send a copy of such accounting to Novartis. The Parties shall jointly determine (within [***] thereafter) the appropriate reimbursement from Novartis so that the total Direct Costs for the Quarter in accordance with the Budget are paid by Novartis, and Olema shall issue an Invoice for the agreed-upon amount. All payments shall be made [***] of the relevant Invoices. Olema shall maintain accurate records and book of account relating to this Agreement in accordance with accepted accounting practices to ensure the funds provided by Novartis are spent in accordance with this Agreement. Olema shall make such records and books available to Novartis upon reasonable advance written notice and at Novartis' expense during Olema's normal business hours, under conditions of confidentiality, but not more frequent than once each calendar year.

5.4 Other Clinical Trials. Nothing in this Agreement shall preclude either Party from conducting any other clinical trials as it may determine in its discretion, so long as it does not use or rely on the Confidential Information that is solely owned by the other Party in doing so**.**

ARTICLE 6

INTELLECTUAL PROPERTY

6.1 Background Technology. Olema retains and shall retain and reserve all rights in and to all Olema Background Technology and Olema Background Patent Rights, subject only to the limited license rights expressly granted to Novartis in this Agreement. Novartis retains and shall retain and reserve all rights in and to all Novartis Background Technology and Novartis Background Patent Rights, subject only to the limited license rights expressly granted to Novartis in this Agreement.

6.2 Inventions and related Patent Rights. All rights to Study Inventions are and shall be allocated as follows:

(a) Olema Ownership. Subject to the terms of this Agreement, all Olema Study Inventions (including all IP rights therein) and Olema Study Patent Rights are and shall be owned solely by Olema, and Olema will have the full right to exploit such Olema Study Inventions and Olema Study Patent Rights without the consent of, or any obligation to account to, Novartis. Novartis shall assign and hereby assigns (and shall cause its Affiliates and contractors to assign) the entire rights, title and interests in any Olema Study Inventions (including all IP rights therein) and Olema Study Patent Rights to Olema. Novartis shall execute such further documents and provide other assistance as may be reasonably requested by Olema to perfect Olema's rights in all such Olema Study Inventions and Olema Study Patent Rights, all at Olema's expense. Olema shall have the sole right, but not any obligation, to Prosecute and maintain any Olema Study Patent Rights at its own expense.

(b) Novartis Ownership. Subject to the terms of this Agreement, all Novartis Study Inventions (including all IP rights therein) and Novartis Study Patent Rights are and shall be owned solely by Novartis, and Novartis will have the full right to exploit such Novartis Study Inventions and Novartis Study Patent Rights without the consent of, or any obligation to account to, Olema. Subject to the provisions of Olema's agreements with Trial Sites pertaining to the Combined Therapy Clinical Trials to the contrary (which agreements Olema hereby represents and warrants will not contain terms materially less preferential to Novartis' ownership of Novartis Study Inventions and joint ownership of Combined Therapy Inventions than terms therein governing Olema's ownership of Olema Study Inventions and joint ownership of Combined Therapy Inventions), Olema shall assign and hereby assigns (and shall cause its Affiliates and contractors to assign) all its right, title and interest in any Novartis Study Inventions and Novartis Study Patent Rights to Novartis. Olema shall execute such further documents and provide other assistance as may be reasonably requested by Novartis to perfect Novartis' rights in such Novartis Study Inventions and Novartis Study Patent Rights, all at Novartis' expense. Novartis shall have the sole right but not the obligation to Prosecute and maintain any Novartis Study Patent Rights at its own expense.

(c) Combined Therapy Inventions.

(i) Subject to the provisions of Olema's agreements with Trial Sites pertaining to the Combined Therapy Clinical Trials to the contrary (which agreements Olema hereby represents and warrants will not contain terms materially less preferential to Novartis' ownership of Novartis Study Inventions and joint ownership of Combined Therapy Inventions than terms therein governing Olema's ownership of Olema Study Inventions and joint ownership of Combined Therapy Inventions), all Combined Therapy Inventions (including all IP rights therein) and Combined Therapy Patent Rights shall be jointly owned by the Parties, with each Party having an undivided one-half interest in all Combined Therapy Inventions and Combined Therapy Patent Rights, and each Party shall have the right to freely exploit, in the Territory, the Combined Therapy Inventions and Combined Therapy Patent Rights, both within and outside the scope of this Agreement, without the consent of, or accounting or any

other obligation to, the other Party (except as expressly set forth in this Section 6.2(c) and Section 6.2(d) with regard to the Prosecution, maintenance and enforcement of Combined Therapy Patent Rights) and each Party may use, exploit and grant licenses (with right to sublicense), for use and exploitation in the Territory, to Third Parties under its interests in such Combined Therapy Inventions and Combined Therapy Patent Rights.

(ii) [***], using outside counsel selected by [***], shall have the sole rights and responsibility (except as otherwise provided below), and at its sole discretion, for Prosecuting patent applications, and maintaining issued Patents, within the Territory that Cover potentially patentable inventions within the Combined Therapy Inventions. [***] shall keep [***] reasonably advised as to material developments and steps to be taken with respect to its Prosecuting any such Patent Rights and shall furnish [***] with copies of applications for such Combined Therapy Patent Rights, amendments thereto and other related material correspondence to and from patent offices, and permit [***] a reasonable opportunity to review and offer comments prior to submitting such applications and material correspondence to the applicable governmental authority (and will take [***] comments into account in preparing same). [***] shall reasonably assist and cooperate in [***] Prosecuting and maintaining the Combined Therapy Patent Rights, including the timely provision of all documents in [***] possession required under national provisions to register said assignment of rights with the corresponding national authorities. Notwithstanding the foregoing, [***] shall not knowingly take any position in a submission to a patent office concerning a patent application for a Combined Therapy Patent Right that interprets the scope of a claim in a [***] Background Patent Right or [***] Study Patent Right without the prior written consent of [***], such consent not to be unreasonably withheld. [***] shall be reimbursed by [***] for [***] of any costs and expenses incurred in Prosecuting Combined Therapy Patent Rights and the subsequent maintenance of Combined Therapy Patent Rights, such that [***] shall be responsible for [***] of all such costs and expenses. From time-to-time, [***] shall invoice [***] for [***] of the amounts of such costs and expenses incurred, and [***] shall pay [***] such invoiced amounts within [***] after receipt of an invoice therefor. If [***] does not reimburse [***] for [***] of [***] Prosecution costs and expenses incurred by [***] as to a particular Combined Therapy Patent Right in a country within such [***] period, then [***] will send written notice ("Warning Letter") to the [***] contacts listed in Section 12.6 which must contain a statement that [***] failure to pay the stated amount within [***] of the date on the written notice will cause the assignment of [***] Combined Therapy Patent Right to [***]. If [***] does not reimburse [***] for [***] of [***] Prosecution costs and expenses incurred by [***] as to a particular Combined Therapy Patent Right in a country within [***] following the date of the Warning Letter, then [***] shall, on [***] written request, [***].

(iii) The Parties shall discuss in good faith whether and on what terms [***] shall take the lead in Prosecuting any particular Combined Therapy Patent Rights in particular countries. In the event [***] decides not to Prosecute (or continue Prosecution of) a particular Combined Therapy Patent Right in a given country, then [***] shall give [***] written notice of such decision, and in such case [***] shall have the right (but not obligation) to Prosecute and maintain such Combined Therapy Patent Right in such country in its own name and at its own expense. In this case, [***] shall promptly assign its rights to such Combined Therapy Patent Right in said country to [***] solely in such country, and [***] shall grant, and hereby grants, to [***] an irrevocable, perpetual, fully-paid, non-exclusive license, with the right to grant and authorize sublicenses, under such Combined Therapy Patent Rights to make, have made, use, sell, offer for sale, import and other exploit products and services in such country (which license shall survive any expiration or termination of this Agreement), provided [***] has reimbursed [***] for [***] of [***] Prosecution costs and expenses incurred under this subsection (iii). In such case, [***] shall provide [***] reasonable assistance in [***] Prosecution (at [***] expense) of such assigned Combined Therapy Patent Right in such country, including the timely provision of all documents in [***] possession required under national provisions to register said assignment of rights with the corresponding national authorities at the sole expenses of the Party who wishes to file or maintain such Combined Therapy Patent Right in that given country.

(d) Separation of Patent Rights. In order to more efficiently enable the Prosecution and maintenance of the Novartis Study Patent Rights, Olema Study Patent Rights, and the Combined Therapy Patent Rights relating to applicable Study Inventions as provided and described above, the Parties will use good faith efforts to separate Novartis Study Patent Rights, Olema Study Patent Rights, Combined Therapy Patent Rights, Novartis Background Patent Rights and Olema Background Patent Rights into separate patent filings to the extent reasonably possible and without adversely impacting such Prosecution and maintenance or the scope of the protected patentable subject matter.

6.3 Disclosure and Assignment of Inventions. Each Party shall disclose promptly to the other Party in writing and on a confidential basis all Study Inventions prior to any public disclosure thereof or filing of Patent Rights therefor and allowing sufficient time for comment by the other Party. In addition, each Party shall, and does hereby, assign, and shall cause its Affiliates and contractors to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Inventions as well as any Patent Rights and other intellectual property rights with respect thereto, as is necessary to fully effect, as applicable, the sole ownership provided for in Sections 6.2(a) and 6.2(b) and the joint ownership provided for in Section 6.2(c).

6.4 Infringement of Patent Rights by Third Parties.

(a) Notice. Each Party shall promptly notify the other Party in writing of any Infringement of Combined Therapy Patent Rights, of which it becomes aware.

(b) Infringement of Olema Patent Rights. For all Infringements of Olema Study Patent Rights or Olema Background Patent Rights anywhere in the world, Olema shall have the exclusive right to enforce its Patent Rights against such Infringements as it may determine in its sole and absolute discretion (including settling any such enforcements), and Olema shall bear all related expenses and retain all related recoveries. Novartis shall reasonably cooperate with Olema or its designee (to the extent Novartis has relevant information arising out of this Agreement), at Olema's request and expense, in any such action to enforce such Patent Rights.

(c) Infringement of Novartis Patent Rights. For all Infringements of Novartis Study Patent Rights or Novartis Background Patent Rights anywhere in the world, Novartis shall have the exclusive right to enforce its Patent Rights against such Infringements as it may determine in its sole and absolute discretion (including settling any such enforcements), and Novartis shall bear all related expenses and retain all related recoveries. Olema shall reasonably cooperate with Novartis or its designee (to the extent that Olema has relevant information arising out of this Agreement), at Novartis's request and expense, in any such action to enforce such Patent Rights.

(d) Infringement of Combined Therapy Patent Rights.

(i) With respect to Infringements of Combined Therapy Patent Rights, the Parties shall discuss reasonably and mutually agree as to whether to bring an enforcement action to seek the removal or prevention of such Infringements and damages therefor and, if so, which Party shall bring such action, with any costs and expenses relating thereto to be allocated in accordance with Section 6.4(d)(ii).

(ii) Regardless of which Party brings an enforcement action pursuant to Section 6.4(d)(i) or whether the Parties reach agreement to initiate such an enforcement action, the other Party hereby agrees to cooperate reasonably in any such action, including, if required, by bringing a legal action, furnishing a power of attorney or joining as a plaintiff to such a legal action. If the Parties mutually agree to bring an enforcement action, Novartis shall be responsible for [***], and Olema shall be responsible for [***] (or as the Parties otherwise agree in writing), of the reasonable and verifiable external costs and expenses incurred in connection with any such action. If either Party recovers monetary damages from any Third Party in an enforcement action agreed to by the Parties, such recovery shall be allocated first to the reimbursement of any actual, unreimbursed external costs and expenses incurred by either of the Parties in

such litigation pro rata in accordance with the aggregate amounts spent by both Parties, and any remaining amounts shall be split [***] to Olema and [***] to Novartis, unless the Parties agree in writing to a different allocation. If the Parties do not agree to initiating such an enforcement action, then either Party may initiate such action, under the following terms: (A) [***] and (B) [***]. Neither Party shall enter into any settlement of any enforcement action under this Section 6.4(d) without the prior written consent of the other Party, such consent not to be unreasonably withheld.

6.5 Infringement of Third Party Rights.

(a) Notice. If activities conducted by a Party relating to the Combined Therapy Clinical Trials or otherwise pursuant to this Agreement become the subject of a claim of infringement or misappropriation of a patent, copyright or other proprietary right by a Third Party (***"3rd Party Infringement Claim"***) anywhere in the world against a Party, the Party first having notice of the claim shall promptly notify the other Party and, without regard to which Party is charged with said infringement and the venue of such claim, the Parties shall promptly confer to discuss the claim.

(b) Defense. If both Parties are charged with infringement pursuant to a 3rd Party Infringement Claim described in Section 6.5(a), each Party shall have the right to defend itself against such claim, and the Parties shall discuss in good faith defending such claim jointly. If only one Party is charged with infringement in such 3rd Party Infringement Claim, such Party will have the first right but not the obligation to defend such claim. If the charged Party does not commence actions to defend such claim within [***] after request by the other Party to do so, then the other Party shall have the right, but not the obligation, to defend any such claim to the extent such claim pertains to the other Party's Single Agent Compound. In any event, the non-defending Party shall reasonably cooperate with the Party conducting the defense of the 3rd Party Infringement Claim and shall have the right to participate with separate counsel at its own expense (but solely with respect to its interests, and shall not interfere with the defending Party's defense of the claim), and the defending Party shall consider comments and suggestions on strategy for defending the action by the non-defending Party in good faith. The Party defending the claim shall [***] and shall [***]. If the Parties jointly defend the claim, Olema shall bear [***], and Novartis shall bear [***] of any external costs and expenses of the defense of any such Third Party infringement claim; *provided, however, that*, notwithstanding the foregoing, if the claim relates solely to one Party's Compound, such Party will bear one hundred percent (100%) of the costs and expenses of the defense of such claim and shall have the sole right, but not the obligation, to defend, settle and otherwise handle the disposition of such claim. Neither Party shall enter into any settlement of any such Third Party infringement action under this Section 6.5 concerning activities under this Agreement or the Combined Therapy that materially negatively affects the other Party's rights under this Agreement or imposes any material obligations on the other Party, including any admissions of wrongdoing on behalf of the other Party, without such other Party's prior written consent, not to be unreasonably withheld or delayed, except that a Party may settle any claim that solely relates to its Single Agent Compound without the consent of the other Party and Novartis may settle any claim that solely relates to the Novartis Alpelisib Metabolite without the Consent of Olema as long as such other Party's rights under this Agreement are not materially adversely impacted (and in the case such a settlement would materially adversely affect the other Party's rights under this Agreement, such settlement cannot be entered into, unless the Party obtains such other Party's prior written consent, not to be unreasonably withheld or delayed).

6.6 Clinical Trial Regulatory Documentation. Subject to the license and other rights granted by each Party to the other Party pursuant to this Agreement, Olema shall solely own all right, title and interest in and to the Combined Therapy Clinical Trials Regulatory Documentation; *provided, however, that* for clarity, Novartis shall retain sole and exclusive ownership of any Novartis Regulatory Documentation that is submitted with or referenced in the Combined Therapy Clinical Trials Regulatory Documentation and that Olema shall retain sole and exclusive ownership of any Olema Regulatory Documentation that is submitted with or referenced in the Combined Therapy Clinical Trials Regulatory Documentation. This Section 6.6 is without limitation of any other disclosure obligations under this Agreement.

6.7 No Other Use. Except as expressly provided or permitted in Section 6.2, Olema agrees not to apply for any Patent Rights based on or containing Novartis Confidential Information, and to give no assistance to any Third Party for such application without Novartis's prior written authorization, and Novartis agrees not to apply for any Patent Rights based on or containing Olema's Confidential Information, and to give no assistance to any Third Party for such application without Olema's prior written authorization.

6.8 Joint Research Agreement. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in 35 USC § 100 (h).

ARTICLE 7

RECORDS AND STUDY DATA

7.1 Records. Each Party shall maintain complete and accurate records of all work conducted with respect to the Combined Therapy Clinical Trials and of all Study Inventions and Study Data made, discovered or generated by or on behalf of such Party or its Affiliate, or by the Parties together, in the course of such Party's (ies') efforts with respect to the Combined Therapy Clinical Trials. Such records shall fully and properly reflect all work done and results achieved in the performance of the Combined Therapy Clinical Trials in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes.

7.2 Ownership of Study Data. As between Novartis and Olema, (a) Novartis shall own the particular Study Data that relate exclusively to the Novartis Study Drugs and the particular Study Data that relates exclusively to the Novartis Alpelisib Metabolite (collectively, "***Novartis Study Data***"), and Olema shall own the particular Study Data that relate exclusively to Olema Study Drug ("***Olema Study Data***"), and (b) both Parties shall jointly own any and all Study Data that is not Olema Study Data or the Novartis Study Data ("***Combined Therapy Study Data***"). Each Party shall, and does hereby, assign, and shall cause its Affiliates to so assign, to the other Party, without additional compensation, its right, title and interest in and to any Study Data as is necessary to fully effect the foregoing ownership, and agrees to execute all instruments as may be reasonably necessary to effect same.

7.3 Use of Study Data.

(a) Use of a Party's Own Study Data. Novartis may use and analyze the Novartis Study Data for any purpose without obligation or accounting to Olema, who shall hold the Novartis Study Data in confidence pursuant to this Agreement. Olema may use and analyze Olema Study Data for any purpose without obligation or accounting to Novartis, who shall hold Olema Study Data in confidence pursuant to this Agreement.

(b) Use of Combined Therapy Study Data by Novartis. As between Novartis and Olema, Novartis and its Affiliates and (sub)licensees have the rights in the Territory to use, analyze and exploit the Combined Therapy Study Data for all purposes, including in connection with the independent development, commercialization or other exploitation of the Novartis Study Drugs or the Novartis Alpelisib Metabolite (each alone or in combination with other drugs and/or other pharmaceutical agents), without the consent of, or any obligation to account to, Olema; *provided* that nothing in the foregoing grants or shall grant, or is intended or shall be construed as granting, Novartis or its Affiliates or (sub)licensees, any right or license, expressly or impliedly, to make, have made, use, sell, offer for sale, or import Olema Study Drug anywhere in the Territory. Subject to Section 7.5, the results of all such analyses or uses shall be owned by Novartis, including any intellectual property arising out of same, unless the Parties shall have agreed otherwise in a writing separate from this Agreement. The Novartis rights in this subsection (b) are subject to the disclosure limitation in subsection (e) below.

(c) Use of Combined Therapy Study Data by Olema. As between Olema and Novartis, Olema and its Affiliates and (sub)licensees have the rights in the Territory to use, analyze and exploit the Combined Therapy Study Data for all purposes, including in connection with the independent development, commercialization or other exploitation of Olema Study Drug (alone or in combination with other drugs and/or other pharmaceutical agents other than Novartis Study Drugs and the Novartis Alpelisib Metabolite), without the consent of, or any obligation to account to, Novartis; *provided* that nothing in the foregoing grants or shall grant, or is intended or shall be construed as granting, Olema or its Affiliates or (sub)licensees, any right or license, expressly or impliedly, to make, have made, use, sell, offer for sale, or import the Novartis Study Drugs or the Novartis Alpelisib Metabolite in the Territory. Subject to Section 7.5, the results of all such analyses or uses shall be owned by Olema, including any intellectual property arising out of same, unless the Parties shall have agreed otherwise in a writing separate from this Agreement.

(d) [***]. Each Party may use, and may disclose to a Third Party for such use, under obligations of confidentiality consistent with this Agreement, the Combined Therapy Study Data and the Study Data that relate exclusively to its Compound, to [***]. Unless otherwise mutually agreed by the Parties in writing, and except as otherwise agreed with any Third Party, each Party will [***], and if requested by the other Party, it shall, to the extent allowed under applicable Third Party agreements, grant to the other Party a [***]. The Parties will discuss in good faith any opportunities to jointly participate in [***].

(e) Limitation on Disclosure of Data. The Parties agree that, prior to the publication of the Combined Therapy Study Data, neither Party (or its Affiliate or sublicensee) shall publicly disclose such Combined Therapy Study Data without the written agreement of the Parties, such agreement not to be unreasonably withheld if requested by a Party, and subject to Section 8.4. The Parties agree to cooperate reasonably and in good faith, as provided in Section 8.4, for the orderly and prompt publication of the Combined Therapy Study Data, in accordance with industry standards, and with the clinical trial agreements with the Trial Sites that conduct the Combined Therapy Clinical Trials.

7.4 Access to Study Data. Subject to the provisions of this Article 7, each Party shall have access to all Study Data (including de-identified patient records) as and to the extent allowed in Trial Site agreements (which agreements [***]). Olema shall make such Study Data in its possession available to Novartis on a [***] basis within a reasonable period of time, but not to exceed [***], after [***].

7.5 Samples. All Samples shall be [***]. Any such Samples shall be collected in accordance with the applicable Protocol and applicable ICFs. Any data and intellectual property arising out of such Sample use shall be [***]; *provided that*, to the extent that any such data or intellectual property relates solely to the Combined Therapy (or biomarkers solely for use with the Combined Therapy), shall be considered Combined Therapy Study Data, Combined Therapy Inventions and/or Combined Therapy Patent Rights, as the case may be. Samples will be stored for future use in [***] sample repository. If [***], and provided that sufficient quantities of Samples are available and subject to the terms of the applicable ICF and Applicable Law, [***] and, to the extent that such tests are performed, [***]. If the Parties agree that they no longer have a use for the Samples, then the remaining Samples will be destroyed pursuant to [***] standard operating procedures for sample retention and destruction, subject to the terms of and permission(s) granted in the informed consent forms signed by the subjects contributing the Samples in the Combined Therapy Clinical Trials.

ARTICLE 8

CONFIDENTIALITY

8.1 Nondisclosure of Confidential Information.

(a) Prior to the Effective Date, Olema and Novartis entered into that certain Nondisclosure Agreement [***] (the "***CDA***"). As it relates to disclosures pursuant to this Agreement

involving the Novartis Study Drugs, Olema Study Drug or the Combined Therapy solely with respect to conduct of the Combined Therapy Clinical Trials (including plans for such study or its conduct) only, and subject to the provisions of Section 8.7 and Section 12.11 hereof, the CDA is hereby superseded and replaced by the terms of this Agreement, and any Confidential Information disclosed hereunder relating to or for the purpose of conducting the Combined Therapy Clinical Trials disclosed by either Party to the other Party shall be Confidential Information (of the disclosing Party) subject to the terms of this Agreement, and each of the Parties shall treat all such Confidential Information as such in accordance with the terms hereof. All written, visual, oral and electronic data, information, know-how or other proprietary information or materials, both technical and non-technical, disclosed by one Party to any other Party pursuant to this Agreement, or prior to the Effective Date and relating to matters contemplated by this Agreement, and disclosed hereunder, shall be "***Confidential Information***" of the disclosing Party. All Study Data and Study Inventions shall be the Confidential Information of the Party owning such Study Data or Study Invention (as provided in Section 7.2 with regard to Study Data and Section 6.2 with regard to Study Inventions). For purposes of this Agreement, regardless of which Party discloses such Confidential Information to the other, (i) all Olema Study Inventions, Olema Background Technology and Olema Regulatory Documentation shall be Confidential Information of Olema, and Novartis shall be deemed the receiving Party with respect thereto, and (ii) all Novartis Study Inventions, Novartis Background Technology, and Novartis Regulatory Documentation shall be Confidential Information of Novartis, and Olema shall be deemed the receiving Party with respect thereto.

(b) The Parties agree that the terms of this Agreement shall be treated as Confidential Information of each of the Parties, and thus may be disclosed by either Party only as permitted by Section 8.3. Except as required by Applicable Law, each Party agrees not to issue any press release or public statement disclosing information relating to this Agreement or the transactions contemplated hereby or the terms hereof without the prior written consent of the other Party (such consent not to be unreasonably withheld), except as permitted by Sections 8.3 and 8.4.

(c) Except to the extent expressly authorized in this Article 8, or as otherwise agreed in writing by the Parties, each Party agrees that, for the Term and for a period of [***] thereafter, it shall (A) keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement any Confidential Information of the other Party (including information relating to this Agreement or the transactions contemplated hereby or the terms hereof), (B) treat the other Party's Confidential Information with the same degree of care the receiving Party uses for its own confidential information but in no event with less than a reasonable degree of care; and (C) reproduce the disclosing Party's Confidential Information solely to the extent reasonably needed to accomplish the receiving Party's obligations under this Agreement or exercise the receiving Party's rights to use and disclose such Confidential Information as expressly provided for in this Agreement, with all such reproductions being considered the disclosing Party's Confidential Information. Notwithstanding anything to the contrary in this Section 8.1, the receiving Party may disclose the disclosing Party's Confidential Information to its employees, consultants, contractors, agents or permitted (sub)licensees solely on a need-to-know basis for the purpose of fulfilling the receiving Party's obligations under this Agreement and exercising the receiving Party's rights to use and disclose such Confidential Information as expressly provided for in this Agreement; *provided, however, that* (1) any such employees, consultants, agents or permitted (sub)licensees are bound by obligations of confidentiality and non-use at least as restrictive as those set forth in this Agreement, and (2) the receiving Party remains liable for the compliance of such employees, consultants, agents or permitted (sub)licensees with such obligations.

(d) Each receiving Party acknowledges that in connection with its and its representatives examination of the Confidential Information of the disclosing Party, the receiving Party and its representatives may have access to material, non-public information, and that the receiving Party is aware, and will advise its representatives who are informed as to the matters that are the subject of this Agreement, that State and Federal laws, including United States securities laws, may impose restrictions on the dissemination of such information and trading in securities when in possession of such information. Each receiving Party agrees that it will not, and will advise its representatives who are informed as to the

matters that are the subject of this Agreement to not, purchase or sell any security of the disclosing Party on the basis of the Confidential Information of the disclosing Party to the extent such Confidential Information constitute material nonpublic information about the disclosing Party or such security.

(e) Combined Therapy Study Data shall be treated as Confidential Information of each Party and shall not be disclosed to Third Parties except to the extent: (i) it falls within the exceptions set forth in Section 8.2 below, (ii) is authorized under this Section 8.1 or Section 8.3 to be disclosed, (iii) is required to be filed with a Regulatory Authority or included in a product's label or package insert, (iv) is reasonably necessary to be disclosed in order for a Party to exercise its rights under Section 8.3, or (v) is disclosed pursuant to Section 8.4.

8.2 Exceptions. The obligations in Section 8.1 shall not apply with respect to any specific portion of Confidential Information that the receiving Party can demonstrate by contemporaneous tangible records or other competent proof:

(a) was already known to the receiving Party (or its Affiliates), other than under an obligation of confidentiality, either (i) at the time of disclosure by the disclosing Party, or (ii) if applicable, at the time that it was generated hereunder, whichever ((i) or (ii)) is earlier;

(b) was generally available to the public or otherwise part of the public domain either (i) at the time of its disclosure to the receiving Party, or (ii) if applicable, at the time that it was generated hereunder, whichever ((i) or (ii)) is earlier;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) was disclosed to the receiving Party (or its Affiliates), other than under an obligation of confidentiality, by a Third Party who had no obligation to the Party owning or Controlling the information not to disclose such information to others; or

(e) was independently discovered or developed by the receiving Party (or its Affiliates) without the use of, or reference to, the Confidential Information of the disclosing Party.

8.3 Authorized Disclosure. Notwithstanding any other provision of this Agreement and excluding Novartis Confidential Information related to the Novartis Alpelisib Metabolite for Section 8.3(a), (b), and (g) herein, each Party may disclose particular Confidential Information of the other Party to the extent such disclosure is reasonably necessary in the following instances:

(a) filing or prosecuting Patent Rights pursuant to Section 6.2(c);

(b) prosecuting or defending litigation;

(c) complying with Applicable Law or the rules or regulations of any securities exchange on which such Party's stock is listed;

(d) disclosure, in connection with the performance of this Agreement, to Affiliates, permitted (sub)licensees, contractors, IRBs, CROs, academic institutions, consultants, agents, investigators, and employees and contractors engaged by Study Sites and investigators involved with the Combined Therapy Clinical Trials, each of whom prior to disclosure must be bound by terms of confidentiality and non-use at least as protective of Confidential Information as those set forth in this Article 8;

(e) disclosure of the Combined Therapy Study Data, Combined Therapy Inventions and Combined Therapy Patent Rights to Regulatory Authorities in connection with the development of the Combined Therapy, Olema Study Drug or the Novartis Study Drugs;

(f) disclosure of relevant safety information contained within the Combined Therapy Study Data to investigators, IRBs and/or ethics committees and Regulatory Authorities that are involved in other clinical trials of Olema Study Drug with respect to Olema, and the Novartis Study Drugs with respect to Novartis, and, in the event of a Material Safety Issue, to Third Parties that are collaborating with Olema or Novartis, respectively in the conduct of such other clinical trials of Olema Study Drug or the Novartis Study Drugs, in each case solely to the extent necessary for the conduct of such clinical trials and/or to comply with Applicable Law and regulatory requirements; and

(g) disclosure of Combined Therapy Study Data, Combined Therapy Inventions and Combined Therapy Patent Rights, and the terms of this Agreement, to prospective (sub)licensees, strategic partners, acquirers, or merger partners, and their respective professional advisors, in connection with discussions of a possible transaction with the disclosing Party and solely for use in due diligence review and evaluation in connection with the negotiation of such transaction, and provided that such recipients must be bound by terms of confidentiality and non-use at least as protective of Confidential Information as those set forth in this Article 8.

Notwithstanding the foregoing, if a Party is required or otherwise intends to make a disclosure of any other Party's Confidential Information pursuant to Section 8.3(b) and/or Section 8.3(c), it shall give advance notice to such other Party of such impending disclosure and endeavor in good faith to secure confidential treatment of such Confidential Information and/or reasonably assist the Party that owns such Confidential Information in seeking a protective order or other confidential treatment.

8.4 Press Releases and Publications.

(a) The Parties shall jointly agree (such agreement not to be unreasonably withheld by either Party) to the content and timing of all public communications with respect to this Agreement (including without limitation press release(s) pertaining to execution of this Agreement (if any) and other press releases), Q&As, and the content of, and wording for, any listing of the Combined Therapy Clinical Trials required to be listed on a public database or other public registry (such as www.clinicaltrials.gov). For clarity, if either Party terminates this Agreement pursuant to Section 11.4, the Parties shall mutually agree upon any external communication related to such termination, which shall not include the rationale for such termination unless (and to the extent) mutually agreed by the Parties; *provided that* either Party shall be permitted to publicly disclose information that such Party determines in good faith is necessary to be disclosed to comply with Applicable Law or the rules or regulations of any securities exchange on which such Party's stock may be listed, or pursuant to an order of a court or governmental entity.

(b) Olema shall have the exclusive right to publicly disclose, publish or present (i) top-line results from the Combined Therapy Clinical Trials, limited [***], solely for the purpose of disclosing, as soon as reasonably practicable, the safety or efficacy results and conclusions that are material to either Party under applicable securities laws, and (ii) the conclusions and outcomes of the Combined Therapy Clinical Trials (the "***Results***"), as set forth in the Final Study Report, at a scientific conference as soon as reasonably practicable following the completion of such Combined Therapy Clinical Trials, subject in the case of (ii) to the following terms and conditions. Olema shall deliver to Novartis a copy of the proposed disclosure, publication or presentation at least [***] before submission to a Third Party. Novartis shall determine whether any of its Confidential Information that is contained in such proposed disclosure, publication or presentation should be modified or deleted, and whether to file a patent application on any Novartis Study Invention disclosed therein. The disclosure, publication or presentation shall be delayed for an additional [***] (i.e., a total [***] from the initial proposal) if Novartis reasonably requests such extension to allow time for the preparation and filing of relevant patent applications directed to a Novartis Study Invention. If Novartis reasonably requests modifications to the disclosure, publication or presentation to prevent the disclosure of Confidential Information of Novartis (other than the Results or Combined Therapy Study Data), Olema shall [***]. In the event of a disagreement as to content, timing and/or venue or forum for any disclosure, publication or presentation of the Results, such dispute (a "***Publication Dispute***") shall be referred to the Executive Officers (or their respective designees); provided

that, in the absence of agreement after such good faith discussions, and upon expiration of the additional [***]-period, (A) academic collaborators or Study Sites engaged by Olema in connection with the performance of the Combined Therapy Clinical Trials may publish Combined Therapy Study Data obtained by such academic collaborator or Study Site solely to the extent that such ability to publish such Combined Therapy Study Data is set forth in an agreement between Olema and such academic collaborator or Study Site relating to the conduct of Combined Therapy Clinical Trials and (B) Olema may proceed with the disclosure, publication or presentation provided that such disclosure, publication or presentation is consistent with its internal publication guidelines and customary industry practices for the publication of similar data and does not disclose the Confidential Information of Novartis (other than the Results or Combined Therapy Study Data). Authorship of any publication shall be determined based on the accepted standards used in peer-reviewed academic journals at the time of the proposed disclosure, publication or presentation. The Parties agree that they shall make reasonable efforts to prevent publication of a press release that could jeopardize the future publication of Study Data at a scientific conference or in a scientific journal but in no way will this or any other provision of this Agreement supersede the requirements of any Applicable Law or the rules or regulations of any securities exchange or listing entity on which a Party's stock is listed (including any such rule or regulation that may require a Party to make public disclosures about interim results of the Combined Therapy Clinical Trials).

(c) Olema agrees to include in all press releases, presentations and publications it makes related to the Combined Therapy Clinical Trials specific mention, if applicable, of the Novartis Study Drugs and the support and involvement of Novartis. Subject to the limitation set forth in this Section 8.4, Novartis agrees to include in all press releases, presentations and publications it makes related to the Combined Therapy Clinical Trials specific mention, if applicable, of Olema Study Drug and the support and involvement of Olema.

8.5 Compliance with Sunshine Laws.

(a) As between the Parties, as and when applicable, each Party (as the "Reporting Party") will report payments or other transfers of value ("***POTV***") made by the other Party or its contractor(s) related to the conduct of the Combined Therapy Clinical Trials and any applicable associated contractor engagements as required under the Sunshine Laws for the Combined Therapy Clinical Trials. Novartis shall request delayed publication for any reported POTV for studies sponsored by Olema as permitted under the Sunshine Laws and if consistent with Novartis's normal business practices. In the event that Olema becomes responsible for reporting POTV for studies sponsored by it in a given country during the Term, Olema shall provide written notification to Novartis and the Parties will meet to confer to discuss how they wish to handle reporting thereafter. Interpretation of the Sunshine Laws for purposes of reporting any POTV by a Party shall be in such Party's sole discretion so long as the interpretation complies with Applicable Law.

(b) Olema (i) will provide (to the extent in the possession of Olema), or will utilize Commercially Reasonable Efforts to obligate and ensure that each CRO and other applicable Third Party contractors for the Combined Therapy Clinical Trials provides, Novartis with any information requested by Novartis as Novartis may reasonably determine is necessary for Novartis to comply with its reporting obligations under Sunshine Laws (with such amounts paid to, or at the direction of, healthcare providers, teaching hospitals and/or any other persons for whom POTVs must be reported under Sunshine Laws to be reported to Novartis within a reasonable time period specified by Novartis) and (ii) will reasonably cooperate with, and will utilize Commercially Reasonable Efforts to obligate and ensure that each CRO and other applicable Third Party contractors for the Combined Therapy Clinical Trials reasonably cooperates with, Novartis in connection with its compliance with such Sunshine Laws. The form in which Olema provides any such information shall be mutually agreed but sufficient to enable Novartis to comply with its reporting obligations and Novartis may disclose any information that it believes is necessary to comply with Sunshine Laws. Without limiting the foregoing, Novartis shall have the right to allocate POTVs in connection with this Agreement in any required reporting under Sunshine Laws in accordance with its normal business practices. These obligations shall survive the expiration and termination of this

Agreement to the extent necessary for Novartis to comply with Sunshine Laws. Olema shall not be required to provide any information to Novartis that is subject to disclosure pursuant to Olema's own obligations under the Sunshine Laws. The provisions of this Section 8.5(b) shall be applicable mutatis mutandis, with respect to each Party's obligations herein, in connection with Olema's reporting of POTV under the Sunshine Laws as and when applicable to Olema.

(c) For purposes of this Section 8.5, "***Sunshine Laws***" shall mean Applicable Laws requiring collection, reporting and disclosure of POTVs to certain healthcare providers, entities and individuals. These Applicable Laws may include relevant provisions of the Patient Protection and Affordable Health Care Act of 2010 and implementing regulations thereunder.

8.6 Destruction of Confidential Information. Upon expiration or termination of the Agreement, the receiving Party shall, upon request by the other Party, immediately destroy or return all of the other Party's Confidential Information relating solely to the other Party's Compound as monotherapy (but not to the Combined Therapy or the Combined Therapy Study Data) and Olema shall, upon request by Novartis immediately destroy or return all of Novartis's Confidential information relating to the Novartis Alpelisib Metabolite in its possession; *provided, however, that* the receiving Party shall be entitled to retain one (1) copy of Confidential Information solely for record-keeping purposes, or as needed to exercise its surviving rights under this Agreement, and shall not be required to destroy any Confidential Information required, or reasonably necessary, to be retained for any clinical trial activities that continue after expiration or termination, or off-site computer files created during automatic system back up which are subsequently stored securely by the receiving Party.

ARTICLE 9

REPRESENTATIONS AND WARRANTIES

9.1 Authority and Binding Agreement. Each Party represents and warrants to the other Party as of the Effective Date that (a) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder, (b) it has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder, and (c) the Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party that is enforceable against it in accordance with its terms subject to bankruptcy, insolvency, reorganization, arrangement, winding-up, moratorium, and similar laws of general application affecting the enforcement of creditors' rights generally, and subject to general equitable principles, including the fact that the availability of equitable remedies, such as injunctive relief or specific performance, is in the discretion of the court.

9.2 No Conflicts. Each Party represents and warrants to the other Party as of the Effective Date that, to the best of its knowledge, it has not entered, and shall not enter, into any agreement with any Third Party that is in conflict with the rights granted to the other Party under this Agreement, and has not taken any action that would in any way prevent it from granting the rights granted to the other Party under this Agreement, or that would otherwise materially conflict with the rights granted to the other Party under this Agreement.

9.3 Litigation. Each Party represents and warrants to the other Party as of the Effective Date that, to the best of its knowledge, it is not aware of any pending or threatened litigation (and has not received any written communication) that alleges that its activities related to this Agreement have violated, or that by conducting the activities as contemplated in this Agreement it would violate, any of the intellectual property rights of any other Person (after giving effect to the license grants in this Agreement).

9.4 No Adverse Proceedings. Each Party represents and warrants to the other Party as of the Effective Date that, except as otherwise notified to the other Party, there is not pending or, to the knowledge of such Party, threatened, against such Party, any claim, suit, action or governmental proceeding that would,

if adversely determined, materially impair the ability of such Party to perform its obligations under this Agreement.

9.5 Consents. Each Party represents and warrants to the other Party as of the Effective Date that, to the best of its knowledge, all necessary consents, approvals and authorizations of all regulatory and governmental authorities and other Persons (a) required to be obtained by such Party in connection with the execution and delivery of this Agreement have been obtained and (b) required to be obtained by such Party in connection with the performance of its obligations under this Agreement have been obtained or will be obtained prior to such performance.

9.6 No Debarment. Each Party hereby certifies to the other that it has not used, and will not use the services of any person disqualified, debarred, banned, subject to debarment or convicted of a crime for which a person could be debarred by the FDA under 21 U.S.C. 335a, as amended (or subject to a similar sanction of any other Regulatory Authority), in any capacity in connection with any of the services or work provided under the Combined Therapy Clinical Trials and that this certification may be relied upon in any applications to the FDA or any other Regulatory Authority. It is understood and agreed that this certification imposes a continuing obligation upon each Party to notify the other promptly of any change in the truth of this certification. Upon request by a Party, the other Party agrees to provide a list of persons used to perform the services or work provided under any activities conducted for or on behalf of such Party or any of its Affiliates pursuant to this Agreement who, within the five (5) years preceding the Effective Date, or subsequent to the Effective Date, were or are convicted of one of the criminal offenses required by 21 U.S.C. 335a, as amended, to be listed in any application for approval of an abbreviated application for drug approval.

9.7 Compliance with Applicable Law. Each Party represents and warrants to the other Party that it shall comply with all Applicable Law of the country or other jurisdiction, or any court or agency thereof, applicable to the performance of its activities hereunder or any obligation or transaction hereunder, including those pertaining to the production and handling of drug products, such as those set forth by the Regulatory Authorities, as applicable, and the applicable terms of this Agreement in the performance of its obligations hereunder.

9.8 Affiliates. Each Party represents and warrants to the other Party that, to the extent the intellectual property, Regulatory Documentation or Technology licensed by it hereunder are Controlled by its Affiliates or a Third Party, it has the right to use, and has the right to grant (sub)licenses to the other Party to use, such intellectual property, Regulatory Documentation or Technology in accordance with the terms of this Agreement.

9.9 Ethical Business Practices. Each Party represents and warrants to the other Party that neither it nor its Affiliates will make any payment, either directly or indirectly, of money or other assets, including the compensation such Party derives from this Agreement (collectively a "***Payment***"), to government or political party officials, officials of International Public Organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing (collectively "***Officials***") where such Payment would constitute violation of any law, including the Foreign Corrupt Practices Act of 1977, 15 U.S.C. §§ 78dd-1, et seq. In addition, regardless of legality, neither it nor its Affiliates will make any Payment either directly or indirectly to Officials if such Payment is for the purpose of improperly influencing decisions or actions with respect to the subject matter of this Agreement. All activities will be conducted in compliance with the U.S. False Claims Act and the U.S. Anti-Kickback Statute.

9.10 Single Agent Compound Safety Issues. Each Party represents and warrants as of the Effective Date that, to the best of its knowledge, it is not aware of any material safety or toxicity issue with respect to its Single Agent Compound that are not reflected in the investigator's brochure and/or safety information provided to the other Party for its Single Agent Compound existing as of the Effective Date.

9.11 Compliance with Licensor Agreements. Each Party will use, and will cause its Affiliates

to use, Commercially Reasonable Efforts to comply with its obligations under any agreements entered into by it or its Affiliates with a Third Party under which it is licensed any intellectual property rights or confidential information relating to its Compound (and not to voluntarily terminate same) to the extent necessary for the Combined Therapy Clinical Trials to be conducted and completed in accordance with the terms of this Agreement and for the other Party to receive the rights and benefits provided to it under this Agreement.

9.12 Novartis Drug Warranty. Novartis represents and warrants that the Novartis Study Drugs manufactured and supplied hereunder shall, at the time of Delivery: (a) comply with the specifications for such drug product (as set forth in the regulatory approvals for such product; (b) shall have been manufactured in accordance with all Applicable Laws; and (c) shall not be adulterated or misbranded as such terms are defined in accordance with Applicable Laws.

9.13 DISCLAIMER OF WARRANTY. THE EXPRESS REPRESENTATIONS AND WARRANTIES STATED IN THIS ARTICLE 10 ARE IN LIEU OF, AND THE PARTIES DO HEREBY DISCLAIM, ALL OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED OR STATUTORY, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR USE, AND NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS.

ARTICLE 10

INDEMNIFICATION

10.1 Novartis Indemnification. Novartis hereby agrees to defend, hold harmless and indemnify (collectively, "***Indemnify***") Olema, its Affiliates, and its and their agents, directors, officers, employees and subcontractors (the "***Olema Indemnitees***") from and against any and all liabilities, judgments, costs, expenses and/or losses, including reasonable legal expenses and attorneys' fees (collectively "***Losses***") resulting from Third Party suits, claims, actions, allegations and demands (each, a "***Third Party Claim***") against a Olema Indemnitee to the extent that they arise or result from (a) the negligence or intentional misconduct of any Novartis Indemnitee or any (sub)licensee of Novartis (or its Affiliate) conducting activities on behalf of Novartis (or its Affiliate) under this Agreement, (b) any breach by Novartis of any provision of this Agreement, (c) any injury to a subject in the Combined Therapy Clinical Trials to the extent attributable to the Novartis Study Drugs, or (d) the use by Novartis, its Affiliates, contractors or (sub)licensees of Combined Therapy Study Data, Novartis Study Data, Novartis Study Inventions, Novartis Study Patent Rights, Combined Therapy Inventions and Combined Therapy Patent Rights; but excluding, in each case ((a) through (d)), any such Losses to the extent arising or resulting from a cause or event for which Olema is obligated to Indemnify the Novartis Indemnitees pursuant to Section 10.2.

10.2 Olema Indemnification. Olema hereby agrees to Indemnify Novartis, its Affiliates, and its and their agents, directors, officers, employees and subcontractors (the "***Novartis Indemnitees***") from and against any and all Losses resulting from Third Party Claims against a Novartis Indemnitee to the extent that they arise or result from (a) the negligence or intentional misconduct of any Olema Indemnitee or any (sub)licensee of Olema conducting activities on behalf of Olema under this Agreement, (b) any breach by Olema of any provision of this Agreement, (c) any injury to a subject in the Combined Therapy Clinical Trials to the extent attributable to the Olema Study Drug), or (d) the use by Olema, its Affiliates, contractors or (sub)licensees of Combined Therapy Study Data, Olema Study Data, Olema Study Inventions, Olema Study Patent Rights, Combined Therapy Inventions and Combined Therapy Patent Rights; but excluding, in each case ((a) through (d)), any such Losses or Third Party Claims to the extent arising or resulting from a cause or event for which Novartis is obligated to Indemnify Olema Indemnitees pursuant to Section 10.1.

10.3 Indemnification Procedure. Each Party's agreement to Indemnify the other Party is conditioned on the performance of the following by the Party seeking indemnification: (a) providing written notice to the Indemnifying Party of any Loss and/or Third Party Claim of the types set forth in Section 10.1 and 10.2 promptly, and in any event within [***], after the Party seeking indemnification has knowledge of

such Loss and/or Third Party Claim; *provided that*, any delay in complying with the requirements of this clause (a) will only limit the Indemnifying Party's obligation to the extent of the prejudice caused to the Indemnifying Party by such delay, (b) permitting the Indemnifying Party to assume full responsibility to investigate, prepare for and defend against any such Loss and/or Third Party Claim, (c) providing reasonable assistance to the Indemnifying Party, at the Indemnifying Party's expense, in the investigation of, preparation for and defense of any Loss and/or Third Party Claim, and (d) not compromising or settling such Loss and/or Third Party Claim without the Indemnifying Party's written consent, such consent not to be unreasonably withheld or delayed.

10.4 Separate Defense of Claims. In the event that the Parties cannot agree as to the application of Sections 10.1 and/or 10.2 to any particular Loss or Third Party Claims, the Parties may conduct separate defenses of such Loss and Third Party Claim. Each Party further reserves the right to claim indemnity from the other in accordance with Sections 10.1 and/or 10.2 upon resolution of the underlying Third Party Claim, notwithstanding the provisions of Section 10.3(b).

10.5 Insurance. Each Party shall maintain commercially reasonable levels of insurance or other adequate and commercially reasonable forms of protection or self-insurance to satisfy its indemnification obligations under this Agreement or as required by law. Each Party shall provide the other Party with written notice at least [***] prior to the cancellation, non-renewal or material change in such insurance or self-insurance which would materially adversely affect the rights of the other Party hereunder. The maintenance of any insurance shall not constitute any limit or restriction on damages available to a Party under this Agreement.

10.6 LIMITATION OF LIABILITY. EXCEPT FOR DAMAGES AVAILABLE FOR BREACH OF THE CONFIDENTIALITY OR NON-USE OBLIGATIONS IN ARTICLE 8, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, PUNITIVE, CONSEQUENTIAL OR SPECIAL DAMAGES, INCLUDING LOST PROFITS, ARISING FROM OR RELATING TO THIS AGREEMENT AND/OR SUCH PARTY'S PERFORMANCE HEREUNDER, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES AND REGARDLESS OF THE CAUSE OF ACTION (WHETHER IN CONTRACT, TORT, BREACH OF WARRANTY OR OTHERWISE). NOTHING IN THIS SECTION 10.6 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF A PARTY UNDER SECTIONS 10.1 OR 10.2.

ARTICLE 11

TERM AND TERMINATION

11.1 Term. This Agreement shall be effective as of the Effective Date and shall continue in effect until completion of all activities outlined in the Development Plan and the Protocols, including the completion of all Combined Therapy Clinical Trials by all centers participating in the Combined Therapy Clinical Trials, delivery of all Study Data to the Parties, including all completed case report forms, all final analyses and all final clinical study reports contemplated by the Combined Therapy Clinical Trials to both Parties, and the completion of any statistical analyses and bioanalyses contemplated by the applicable Protocol or otherwise agreed to by the Parties to be conducted under this Agreement, or until earlier termination pursuant to Sections 11.2, 11.3 or 11.4 or any other termination right expressly stated in this Agreement (such period, the "***Term***").

11.2 Termination for Material Breach.

(a) Notice and Cure Period. If a Party (the "***Breaching Party***") is in material breach of its obligations under this Agreement, the other Party (the "***Non-Breaching Party***") shall have the right to give the Breaching Party notice specifying in reasonable detail the nature of such material breach (a "***Breach Notice***"). The Breaching Party shall have a period of [***] after receipt of such notice to cure such material breach (the "***Cure Period***"). For the avoidance of doubt, this provision is not intended to restrict

in any way either Party's right to notify the other Party of any other breach or to demand the cure of any other breach.

(b) Termination Right. If a Breach Notice is given, the Non-Breaching Party giving such notice shall have the right to terminate this Agreement (except as otherwise provided below in this subsection (b)), upon written notice to the other Party given no later than [***] after the end of the applicable Cure Period, in the event that the Breaching Party has not cured the material breach that is the subject of the Breach Notice within the Cure Period, *provided, however, that* if such breach is capable of cure but cannot be cured using reasonable diligent efforts within the Cure Period, and the Breaching Party commences actions to cure such material breach within the Cure Period and thereafter diligently continue such actions, the Breaching Party shall have an additional [***] to cure such breach (and such [***] period shall be deemed added to the Cure Period in such case. If a Breach Notice is given, and the alleged Breaching Party contests that the alleged material breach happened, and or that the breach has not been cured within the Cure Period, [***].

11.3 Termination for Bankruptcy. A Party may terminate this Agreement if, at any time, the other Party shall file in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or for the appointment of a receiver or trustee of such other Party or of such other Party's assets, or if the other Party proposes a written agreement of composition or extension of its debts, or if the other Party shall be served with an involuntary petition against it, filed in any bankruptcy proceeding, and such petition shall not be dismissed or stayed within [***] after the filing thereof, or if the other Party will propose or be a party to any dissolution or liquidation, or if the other Party shall make an assignment for the benefit of its creditors.

11.4 Termination for Convenience; Termination due to Material Safety Issue; Clinical Hold; Study Termination.

(a) A Party shall have the right to terminate this Agreement immediately (but after meeting and discussing with the other Party in good faith as described in the following sentence) upon written notice if such Party reasonably deems it necessary in order to protect the safety, health or welfare of subjects enrolled in the Combined Therapy Clinical Trials due to the existence of a Material Safety Issue. In the event a Party believes that there is a Material Safety Issue and intends to effect a termination of the Agreement due to such Material Safety Issue, prior to such Party providing written notice of Termination, such Party shall give the other Party written notice of such Material Safety Issue and all material evidence for its belief of the existence thereof, and the members of each Party's medical safety committee (or equivalent) and appropriate senior executives of each Party (with authority over the actions under this Agreement) shall, as soon as reasonably practicable, meet together and discuss in good faith the safety concerns raised by the Party and consider and discuss in good faith the input, questions and advice of the other Party. Should any dispute arise in such discussion, or should the Parties not agree on an appropriate resolution to the noticing Party's safety concerns, [***], and the noticing Party shall [***].

(b) If a Clinical Hold with respect to either the Novartis Study Drugs or Olema Study Drug should arise at any time after the Effective Date, the Parties will meet and discuss the basis for the Clinical Hold, how long the Clinical Hold is expected to last, and how they might address the issue that caused the clinical hold. If, after [***] of discussions following the Clinical Hold, either Party reasonably concludes that the issue adversely impacts the Combined Therapy Clinical Trials and is not solvable or that unacceptable and material additional costs/delays have been and/or will continue to be incurred in the conduct of the Combined Therapy Clinical Trials, then such Party may immediately terminate this Agreement.

(c) Novartis may terminate this Agreement immediately at any time by written notice to Olema in accordance with Section 12.3 (Dispute Resolution). If the Agreement is terminated in accordance with Section 12.3, Novartis shall [***]. Notwithstanding any other provisions of this Agreement, including Section 11.5, Novartis's termination rights pursuant to this Section 11.4(c) are subject to a unanimous decision by the Parties on whether to permit Olema, at its own cost, to continue to act as

Sponsor for any on-going Combined Therapy Clinical Trial. If the Parties unanimously decide to permit Olema to continue to act as Sponsor for any on-going Combined Therapy Clinical Trial at its own cost, then the Parties shall act in good faith to negotiate an amendment to this Agreement to cover such Olema-funded on-going Combined Therapy Clinical Trial. If the Parties do not unanimously decide to permit Olema to continue to act as Sponsor for any on-going Combined Therapy Clinical Trial at its own cost, or if the Parties remain deadlocked for a period of at least [***] with respect to such decision, then Novartis may proceed with such termination without conditions. Subject to the mechanism set forth in this clause (c), Olema shall have the right to terminate this Agreement upon written notice to Novartis in the event that Olema terminates all Combined Therapy Clinical Trials for any reason other than those described in Sections 11.4(a) or 11.4(b) above. Olema's termination rights pursuant to this Section 11.4(c) is subject to a unanimous decision by the Parties on whether Novartis should be permitted to act as Sponsor for any on-going Combined Therapy Clinical Trial. If the Parties unanimously decide to permit Novartis to assume the Sponsor role for any Combined Therapy Clinical Trial, then the Parties shall act in good faith to negotiate an agreement to cover such Novartis-Sponsored Combined Therapy Clinical Trial materially aligned with the terms of this Agreement, mutatis mutandis. If the Parties do not unanimously decide to permit Novartis to assume the Sponsor role for any ongoing Combined Therapy Clinical Trials, or if the Parties remain deadlocked for a period of at least [***] with respect to such decision, then Olema may proceed with such termination, including without limitation termination of all Combined Therapy Clinical Trials. Notwithstanding anything to the contrary in this Agreement, either Party may terminate this Agreement with immediate effect upon written notice to the other Party following a decision by the Parties that the Combined Therapy does not, or based on available evidence is not expected to, achieve a level of efficacy sufficiently superior to either the Novartis Study Drug or the Olema Study Drug as a monotherapy to warrant the continuation of the Combined Therapy Clinical Trial.

11.5 Effect of Termination. Upon expiration or termination of this Agreement, (a) the licenses granted in Sections 3.1 and 3.2 (and any sublicenses granted under Section 3.3) shall terminate except as otherwise expressly provided herein and further except as necessary to complete conduct of such study as required under Applicable Law, and (b) the Parties shall use reasonable efforts to wind down activities under this Agreement in a reasonable manner and avoid incurring any additional expenditures or non-cancellable obligations; *provided that*, in the case of termination pursuant to Section 11.4, Olema may continue to dose subjects enrolled in the Combined Therapy Clinical Trials through completion of the applicable Protocol if dosing is required by the applicable Regulatory Authority(ies) and/or Applicable Law. Any such wind-down activities will include the return to Novartis, or destruction, of all Novartis Study Drugs provided to Olema and not consumed in the Combined Therapy Clinical Trials, except in the event that Olema terminates this Agreement pursuant to Section 11.2 or 11.3, in which case Olema shall continue to have the right to use any Novartis Study Drugs provided to Olema for the conduct of the Combined Therapy Clinical Trials.

11.6 Survival. Provisions which by their terms expressly survive expiration or termination of this Agreement, along with the following Articles and Sections of this Agreement and all definitions relating thereto, shall survive any expiration or termination of this Agreement for any reason: [***].

ARTICLE 12

MISCELLANEOUS

12.1 Entire Agreement. The Parties acknowledge that this Agreement shall govern all activities of the Parties with respect to the Combined Therapy Clinical Trials from the Effective Date forward through the Term. This Agreement, including the Appendixes hereto, and together with the Quality Documentation, sets forth the complete, final and exclusive agreement between the Parties concerning the subject matter hereof and supersedes all prior agreements and understandings between the Parties with respect to such subject matter. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties with respect to such subject matter other than as are set forth in this Agreement. All Appendixes attached hereto are incorporated herein as part of this

Agreement.

12.2 Governing Law. This Agreement shall be governed and construed in accordance with the internal laws of the State of New York, USA, excluding any choice of law rules that may direct the application of the laws of another jurisdiction.

12.3 Dispute Resolution.

(a) The Parties' Designated Clinical Contacts (for clinical and regulatory matters) and the Parties Designated Supply Contacts (for supply matters) shall attempt in good faith to resolve any dispute or concern that either Party may bring to the other Party's attention.

(b) In the event of any dispute, controversy, issue or claim arises between the Parties out of, relating to or in connection with any provision of this Agreement (each a "***Dispute***"), other than [***], that cannot be or is not resolved by the applicable Designated Contacts of each Party within a reasonable time after such Dispute arises, then upon the request of either Party by written notice, the Parties shall refer such Dispute to the Executive Officers for discussion to seek to resolve the Dispute. This Agreement shall remain in effect during the pendency of any such Dispute and any discussions to resolve the Dispute and any dispute resolution actions under this Section 12.3. In the event that no resolution is made by the Executive Officers (or their designee) in good faith negotiations within [***], then [***] Novartis shall have a right to terminate this Agreement with immediate effect and without any liability.

12.4 Injunctive Relief. Notwithstanding anything herein to the contrary, a Party may seek an injunction or other injunctive relief from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss or damage on a provisional basis. For the avoidance of doubt, if either Party (a) discloses Confidential Information of the other Party other than as permitted under Article 8, (b) uses (in the case of Olema) the Novartis Study Drugs or Novartis Background Technology or (in the case of Novartis) Olema Study Drug or Olema Background Technology in any manner other than as expressly permitted under this Agreement or (c) otherwise is in material breach of this Agreement and such material breach could cause immediate harm to the value of Olema Study Drug (if Novartis is in material breach) or the Novartis Study Drugs (if Olema is in material breach), the other Party shall have the right to seek an injunction or other equitable relief precluding the other Party from continuing its activities related to the Combined Therapy Clinical Trials without waiting for the conclusion of the dispute resolution procedures under Section 12.3.

12.5 Force Majeure. A Party shall be excused from the performance of its applicable obligation(s) under this Agreement (other than the payment of monies owed to the other Party) to the extent that such performance is prevented by force majeure, and the non-performing Party promptly provides notice of the prevention to the other Party (including details of the force majeure) and uses reasonable efforts to avoid the effects of such force majeure and to perform the affected obligation(s) to the extent reasonably possible. Such excuse of performance shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition or otherwise perform the affected obligation(s). For purposes of this Agreement, "force majeure" shall mean acts of God, strikes or other concerted acts of workers, civil disturbances, fires, earthquakes, material shortages, disease, acts of terrorism, floods, explosions, riots, war, rebellion, sabotage or failure or default of public utilities or common carriers or similar conditions beyond the reasonable control of the applicable Party. For clarity, notwithstanding the existence of a force majeure impacting a Party's performance hereunder, such Party shall continue performing all its other obligations hereunder, and the other Party shall be excused from performing such of its obligations under this Agreement that it cannot reasonably perform due to the non-performance by the Party due to such force majeure, until such Party completes performance of such obligations that are prevented by such force majeure. In addition, if a Party is excused under this Section 12.5 from performance of its obligation due to a force majeure, and such non-performance is of a material obligation and such non-performance continues for a period of one hundred twenty days, then the

other Party may terminate this Agreement on written notice.

12.6 Notices. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement and shall be deemed to have been sufficiently given for all purposes if such notice is timely and is: (a) mailed by first class certified or registered mail, postage prepaid, return receipt requested, (b) sent by express delivery service, or (c) personally delivered. Unless otherwise specified in writing, the mailing addresses of the Parties shall be as described below.

For Olema:	Olema Pharmaceuticals, Inc. 665 3rd St, San Francisco, CA 94107 Attention: [***]
With a copy to:	Attn: James Shehan Lowenstein Sandler LPP 1251 Avenue of the Americas New York, NY 10020
For Novartis:	Novartis Institutes for BioMedical Research 181 Massachusetts Avenue Cambridge, MA 02139 Attention: [***]
With a copy to:	Novartis Pharmaceuticals Corporation 59 Route 10, East Hanover New Jersey, 07936 Attention: [***]

Any such communication shall be deemed to have been received when delivered. It is understood and agreed that this Section 12.6 is not intended to govern the day-to-day business communications necessary between the Parties in performing their duties, in due course, under the terms of this Agreement.

12.7 No Waiver; Modifications. It is agreed that no waiver by a Party of any breach or default of the other Party of any of its covenants or obligations under this Agreements shall be deemed a waiver as to any subsequent and/or similar breach or default by the other Party. To be binding on the Parties, all amendments or modifications to or of this Agreement must be by a written instrument that is duly executed by an authorized representative of each Party. No amendment or modification of the terms of this Agreement, or release or discharge of a Party's obligation under this Agreement or breach thereof, shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

12.8 No Strict Construction. This Agreement has been prepared jointly and shall not be strictly construed against either Party. No presumption as to construction of this Agreement shall apply against either Party with respect to any ambiguity in the wording of any provision(s) of this Agreement irrespective of which Party may be deemed to have authored the ambiguous provision(s).

12.9 Independent Contractor. The Parties are independent contractors of each other, and the relationship between the Parties hereunder shall not constitute a partnership, joint venture or agency. Neither Party shall be the agent of the other. Neither Party shall have any authority to act for, or on behalf of, the other Party in any matter, except as expressly authorized by the specific terms of this Agreement.

12.10 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, such consent not to be unreasonably withheld, *except* that a Party may make such an assignment without the other Party's consent (i) to an Affiliate, (ii) to a Third Party successor in interest that merges with, consolidates with or acquires

all or substantially all of the assets or voting control of the assigning Party, or (iii) to a Third Party successor in interest that acquires all or substantially all of the rights of the assigning Party to Olema Study Drug, in the case of Olema, or the Novartis Study Drugs, in the case of Novartis. If assigned or transferred to an Affiliate, the assigning/transferring Party shall remain jointly and severally responsible and liable with the assignee/transferee Affiliate for the assigned rights and/or obligations. If assigned to a Third Party, any permitted successor or assignee of rights and/or obligations hereunder shall, in a writing to the other Party, expressly assume performance of such rights and/or obligations. Any purported assignment or attempted assignment by any Party in violation of the terms of this Section 12.10 shall be null and void and of no legal effect.

12.11 Headings. The captions to the several Sections and Articles hereof are not a part of this Agreement, but are included merely for convenience of reference only and shall not affect its meaning or interpretation.

12.12 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 facsimile or electronic (e.g., pdf) signatures and such signatures shall be deemed to bind each Party hereto as if they were original signature.

12.13 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law, and if the rights or obligations of a Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties.

12.14 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 order to perfect any license, assignment or other transfer or any properties or rights under, or pursuant, to this Agreement.

12.15 No Benefit to Third Parties. The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties, their respective Affiliates, and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other parties.

12.16 Construction.

(a) General. Except as otherwise explicitly specified to the contrary, (i) references to a Section, Article or Appendix means a Section or Article of, or Appendix to, this Agreement and all subsections thereof, unless another agreement is specified, (ii) references to a particular statute or regulation include all rules and regulations promulgated thereunder and any successor statute, rules or regulations then in effect, in each case including the then-current amendments thereto, (iii) words in the singular or plural form include the plural and singular form, respectively, (iv) the terms “including,” “include(s),” “such as,” and “for example” used in this Agreement mean including the generality of any description preceding such term and will be deemed to be followed by “without limitation”, (v) the words “hereof,” “herein,” “hereunder,” “hereby” and derivative or similar words refer to this Agreement, (vi) “or” is used in the conjunctive (“and/or”) unless the context requires otherwise, (vii) “will” and “shall” are synonyms, (viii) references to “(sub)licensees” means Third Party licensees or sublicensees of a Party or its Affiliate, and (ix) days means calendar days. No presumption as to construction of this Agreement shall apply against either Party with respect to any ambiguity in the wording of any provision(s) of this Agreement irrespective

of which Party may be deemed to have authored the ambiguous provision(s).

(b) No Response. Except as expressly set forth in this Agreement, where a provision of this Agreement provides for a Party to respond within a designated period following written notice from the other Party, and if such Party fails to respond, then the failure to respond shall not be deemed to create or imply: (i) that the non-responding Party agrees or disagrees with the proposed action to be taken by the other Party, (ii) any amendment, change or waiver of the terms of this Agreement, or (iii) any consent that an action proposed to be taken may be taken if it conflicts with the terms of this Agreement and/or waiver of any rights it may have to seek remedies at law or in equity for breach of this Agreement as a result of the action taken.

[*Signature page follows*]

IN WITNESS WHEREOF, the Parties, intending to be legally bound hereby, have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

Olema Pharmaceuticals Inc.		**Novartis Institutes for BioMedical Research, Inc.**	
By:	/s/ Sean Bohen	By:	/s/ Alice Shaw
Name:	Sean Bohen	Name:	Alice Shaw
Title:	CEO and President	Title:	
Date:	January 13, 2022	Date:	January 19, 2022

APPENDIX A

DEVELOPMENT PLAN[***]

APPENDIX B

Direct Costs Budget

Study Arm					**Est. Total Costs**
	[***]	[***]	[***]	[***]	
OP-1250+Kisqali	[***]	[***]	[***]	[***]	[***]
OP-1250+Piqray	[***]	[***]	[***]	[***]	[***]

1, [***]. NOTE: Estimated Study Total Cost does not include [***]. See below chart.

	[***]	[***]	[***]	[***]	**Est. Total Costs**
Year 1	[***]	[***]	[***]	[***]	[***]
Year 2	[***]	[***]	[***]	[***]	[***]

* excludes [***]

APPENDIX C

Sample Invoice to Novartis

[***]	[***]	[***]

[***]

APPENDIX D
Protocol Synopsis

OLEMA PHARMACEUTICALS	[***]	[***]

[***]

Exhibit 10.2

March 21, 2023

Cyrus Harmon
VIA EMAIL

Dear Cyrus:

This letter sets forth the substance of the separation agreement (the "**Agreement**") that Olema Pharmaceuticals, Inc. (the "**Company**") is offering to you to aid in your employment transition.

1. SEPARATION. Your employment termination date will be March 24, 2023 (the "**Separation Date**"). Notwithstanding the termination of your employment relationship, you will remain a member of the Company's Board of Directors (the "**Board**").

2. ACCRUED SALARY. On the Separation Date, the Company will pay you all accrued salary earned through the Separation Date, subject to standard payroll deductions and withholdings. You are entitled to this payment by law. Because the Company has a nonaccrual vacation/PTO policy, you do not have any accrued vacation or other paid time off and thus will not be paid out for any accrued vacation or other paid time off.

3. SEVERANCE BENEFITS. If you timely sign this Agreement, allow it to become effective, and comply with your obligations under it, then the Company will provide you the following severance benefits:

(a) Severance Payment. The Company will pay you a lump-sum severance payment equal to (i) 12 months of your base salary in effect as of the Separation Date, plus (ii) your target bonus for 2023, prorated based on your months of service as an employee during 2023. This severance payment will be subject to standard payroll deductions and withholdings and paid no later than on the 60th day following the Separation Date.

(b) To the extent provided by the federal COBRA law or, if applicable, state insurance laws, and by the Company's current group health insurance policies, you will be eligible to continue your group health insurance benefits at your own expense following the Separation Date. Later, you may be able to convert to an individual policy through the provider of the Company's health insurance, if you wish. You will be provided with a separate notice describing your rights and obligations under COBRA and a form for electing COBRA coverage. As an additional severance benefit under this Agreement, provided that you timely elect continued coverage under COBRA, then the Company will pay you a lump-sum amount of $51,408 which is equal to the COBRA premiums to continue your health insurance for one year following the Separation Date. This payment will be subject to standard payroll deductions and withholdings and paid with the severance payment under Section 3(a) above. You may, but are not required to, use this payment for health insurance premiums.

4. EQUITY AWARDS. Because your service as a member of the Board will be continuous, your termination of employment will not constitute a termination of service. Thus, vesting of your outstanding equity awards to acquire the Company's common stock (the "**Equity Awards**") will

not cease as of the Separation Date but instead shall continue until your Board service ceases. Your Equity Awards shall continue to be governed by the plans under which they were granted and all applicable grant notices and agreements, except that in the event your service as a Board member ceases prior to the expiration of any Equity Awards, you shall have a 24-month period following cessation of Board service to exercise all then-vested Equity Awards. You understand that any Equity Awards that you hold as of the Separation Date that qualify as "incentive stock options" will cease to qualify as such three months after the Separation Date, and instead will be treated as "nonqualified stock options" for tax withholding and reporting purposes.

5. TAXES AND WITHHOLDING. As a member of the Board, the Company will not withhold any amount for taxes, social security or other payroll deductions relating to your Board service. The Company will issue you a Form 1099 with respect to any compensation resulting from your Board service. Any taxable income resulting from your employment, including taxes upon exercise of nonqualified stock options or settlement of restricted stock units granted to you in your capacity as an employee, will be reported to you as employment income on Form W-2 and be subject to withholding that you will be required to satisfy to the extent required by law. You acknowledge that you will be entirely responsible for payment of any such taxes, and you hereby indemnify, defend and save harmless the Company, and its officers and directors in their individual capacity, from any liability for any taxes, penalties or interest that may be assessed by any taxing authority with respect to all compensation you receive under this Agreement, with the exception of the employer's share of social security, if any.

6. OTHER COMPENSATION OR BENEFITS. You acknowledge that, except as expressly provided in this Agreement, you have not earned and will not receive from the Company any additional compensation (including base salary, bonus, incentive compensation, or equity), severance, or benefits before or after the Separation Date, with the exception of any vested right you may have under the express terms of a written ERISA-qualified benefit plan (e.g., 401(k) account). You further acknowledge and agree that you are accepting the benefits set forth herein in full satisfaction of any severance benefits you are eligible to receive from the Company under any plan or agreement, including (without limitation) under the terms of your November 13, 2020 amended and restated offer letter with the Company.

7. EXPENSE REIMBURSEMENTS. You agree that, within 30 days after the Separation Date, you will submit your final documented expense reimbursement statement reflecting all business expenses you incurred through the Separation Date, if any, for which you seek reimbursement. The Company will reimburse you for these expenses pursuant to its regular business practice.

8. RELEASE OF CLAIMS.

(a) General Release of Claims. In exchange for the consideration provided to you under this Agreement to which you would not otherwise be entitled, you hereby generally and completely release the Company, and its affiliated, related, parent and subsidiary entities, and its and their current and former directors, officers, employees, shareholders, partners, agents, attorneys, predecessors, successors, insurers, affiliates, and assigns from any and all claims,

liabilities, demands, causes of action, and obligations, both known and unknown, arising from or in any way related to events, acts, conduct, or omissions occurring at any time prior to and including the date you sign this Agreement.

(b) Scope of Release. This general release includes, but is not limited to: (i) all claims arising from or in any way related to your employment with the Company or the termination of that employment; (ii) all claims related to your compensation or benefits from the Company, including salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, or any other ownership, equity, or profits interests in the Company; (iii) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (iv) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (v) all federal, state, and local statutory claims, including claims for discrimination, harassment, retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964, the federal Americans with Disabilities Act of 1990, the California Labor Code, the California Family Rights Act, the Age Discrimination in Employment Act ("**ADEA**") and the California Fair Employment and Housing Act. **You acknowledge that you have been advised, as required by California Government Code Section 12964.5(b)(4), that you have the right to consult an attorney regarding this Agreement and that you were given a reasonable time period of not less than five business days in which to do so.** You further acknowledge and agree that, in the event you sign this Agreement prior to the end of the reasonable time period provided by the Company, your decision to accept such shortening of time is knowing and voluntary and is not induced by the Company through fraud, misrepresentation, or a threat to withdraw or alter the offer prior to the expiration of the reasonable time period, or by providing different terms to employees who sign such an agreement prior to the expiration of the time period.

(c) ADEA Release. You acknowledge that you are knowingly and voluntarily waiving and releasing any rights you have under the ADEA, and that the consideration given for the waiver and releases you have given in this Agreement is in addition to anything of value to which you were already entitled. You further acknowledge that you have been advised, as required by the ADEA, that: (i) your waiver and release does not apply to any rights or claims arising after the date you sign this Agreement; (ii) you should consult with an attorney prior to signing this Agreement (although you may choose voluntarily not to do so); (iii) you have 21 days to consider this Agreement (although you may choose voluntarily to sign it sooner); (iv) you have seven days following the date you sign this Agreement to revoke this Agreement (in a written revocation sent to me); and (v) this Agreement will not be effective until the date upon which the revocation period has expired, which will be the eighth day after you sign this Agreement provided that you do not revoke it (the "**Effective Date**").

(d) Section 1542 Waiver. In giving the release herein, which includes claims that may be unknown to you at present, you acknowledge that you have read and understand Section 1542 of the California Civil Code, which reads as follows: **"A general release does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party."** You hereby

expressly waive and relinquish all rights and benefits under that section and any law of any other jurisdiction of similar effect with respect to your release of claims herein, including but not limited to your release of unknown claims.

(e) Exceptions. Notwithstanding the foregoing, you are not releasing the Company hereby from: (i) any obligation to indemnify you pursuant to the Certificate of Incorporation and Bylaws of the Company, any valid fully executed indemnification agreement with the Company, applicable law, or applicable directors and officers liability insurance; (ii) any claims that cannot be waived by law; or (iii) any claims for breach of this Agreement.

(f) Protected Rights. You understand that nothing in this Agreement limits your ability to file a charge or complaint with the Equal Employment Opportunity Commission, the Department of Labor, the National Labor Relations Board, the Occupational Safety and Health Administration, the California Department of Fair Employment and Housing, the Securities and Exchange Commission or any other federal, state or local governmental agency or commission ("**Government Agencies**"). You further understand this Agreement does not limit your ability to communicate with any Government Agencies or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including providing documents or other information, without notice to the Company. While this Agreement does not limit your right to receive an award for information provided to the Securities and Exchange Commission, you understand and agree that, to maximum extent permitted by law, you are otherwise waiving any and all rights you may have to individual relief based on any claims that you have released and any rights you have waived by signing this Agreement. Nothing in this Agreement (i) prevents you from discussing or disclosing information about unlawful acts in the workplace, such as harassment or discrimination or any other conduct that you have reason to believe is unlawful; or (ii) waives any rights you may have under Section 7 of the National Labor Relations Act (subject to the release of claims set forth herein).

9. RETURN OF COMPANY PROPERTY. Following your Separation Date, it is agreed that you will provide focused ongoing support to the Company, at the direction of the Chief Executive Officer, relating to the drafting and preparation of a scientific manuscript ("Manuscript Drafting") targeted for submission to a leading peer reviewed scientific journal by June 30, 2023. Excepting Company documents and information (i) expressly identified by you as needed for the Manuscript Drafting, or (ii) which you have obtained via the Olema Board portal or otherwise and which you believe are relevant as part of your ongoing non-employee Board Director role, you agree that within ten days after the Separation Date, you will return to the Company all Company documents (and all copies thereof) and other Company property which to your knowledge is in your possession or control, including, but not limited to, Company files, notes, drawings, records, plans, forecasts, reports, studies, analyses, proposals, agreements, drafts, financial and operational information, research and development information, sales and marketing information, customer lists, prospect information, pipeline reports, sales reports, personnel information, specifications, code, software, databases, computer-recorded information, tangible property and equipment (including, but not limited to, computing and electronic devices, laptop(s) with Company information, mobile telephones, servers), credit cards, entry cards, identification badges and keys; and any materials of any kind that contain or embody any proprietary or confidential information

of the Company (and all reproductions or embodiments thereof in whole or in part). You will work with the Chief Executive Officer or his designee on identifying what Company documents and information you need for Manuscript Drafting, and the return of that information upon submission of the manuscript to the peer reviewed scientific journal for publication; provided that the Olema property specifically listed in Exhibit A will be transferred to you on the Separation Date at no cost.

10. CONFIDENTIAL INFORMATION OBLIGATIONS. You acknowledge and reaffirm your continuing obligations under your Employee Proprietary Information and Invention Assignment Agreement.

11. NON-DISPARAGEMENT. Except to the extent permitted by Section 8(f), you agree not to disparage the Company or its officers, directors, employees, shareholders, parents, subsidiaries, affiliates, and agents, in any manner likely to be harmful to its or their business, business reputation, or personal reputation; provided that you may respond accurately and fully to any request for information if required by legal process or in connection with a government investigation. In addition, nothing in this provision or this Agreement prohibits or restrains you from making disclosures protected under the whistleblower provisions of federal or state law, or from exercising your rights to engage in protected speech under Section 7 of the National Labor Relations Act, if applicable

12. NO VOLUNTARY ADVERSE ACTION. You agree that you will not voluntarily (except in response to legal compulsion or as permitted under the section of this Agreement entitled "**Protected Rights**") assist any person in bringing or pursuing any proposed or pending litigation, arbitration, administrative claim or other formal proceeding against the Company, its parent or subsidiary entities, affiliates, officers, directors, employees or agents.

13. COOPERATION. You agree to cooperate fully with the Company in connection with its actual or contemplated defense, prosecution, or investigation of any claims or demands by or against third parties, or other matters arising from events, acts, or failures to act that occurred during the period of your employment by the Company. Such cooperation includes, without limitation, making yourself available to the Company upon reasonable notice, without subpoena, to provide complete, truthful and accurate information in witness interviews, depositions, and trial testimony. The Company will reimburse you for reasonable out-of-pocket expenses you incur in connection with any such cooperation (excluding foregone wages) and will make reasonable efforts to accommodate your scheduling needs.

14. NO ADMISSIONS. You understand and agree that the promises and payments in consideration of this Agreement shall not be construed to be an admission of any liability or obligation by the Company to you or to any other person, and that the Company makes no such admission.

15. REPRESENTATIONS. You hereby represent that you have been paid all compensation owed and for all hours worked; received all leave and leave benefits and protections for which you are eligible pursuant to the Family and Medical Leave Act, the California Family

Rights Act, or otherwise; and not suffered any on-the-job injury for which you have not already filed a workers' compensation claim.

16. DISPUTE RESOLUTION. You and the Company agree that any and all disputes, claims, or controversies of any nature whatsoever arising from, or relating to, this Agreement or its interpretation, enforcement, breach, performance or execution, your employment or the termination of such employment (including, but not limited to, any statutory claims), shall be resolved, pursuant to the Federal Arbitration Act, 9 U.S.C. §1-16, and to the fullest extent permitted by law, by final, binding and confidential arbitration in San Francisco, California (or another mutually acceptable location) conducted before a single neutral arbitrator by JAMS, Inc. ("**JAMS**") or its successor, under the then applicable JAMS Arbitration Rules and Procedures for Employment Disputes (available at http://www.jamsadr.com/rules-employment-arbitration/). **By agreeing to this arbitration procedure, both you and the Company waive the right to have any claim resolved through a trial by jury or judge.** You will have the right to be represented by legal counsel at any arbitration proceeding, at your own expense. This paragraph shall not apply to any action or claim that cannot be subject to mandatory arbitration as a matter of law, to the extent such claims are not permitted by applicable law to be submitted to mandatory arbitration and the applicable law(s) are not preempted by the Federal Arbitration Act or otherwise invalid (collectively, the "**Excluded Claims**"). In the event you intend to bring multiple claims, including one of the Excluded Claims listed above, the Excluded Claims may be publicly filed with a court, while any other claims will remain subject to mandatory arbitration. The arbitrator shall have sole authority for determining if a claim is subject to arbitration, and any other procedural questions related to the dispute and bearing on the final disposition. In addition, the arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be available under applicable law in a court proceeding; and (b) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The Company shall pay all JAMS arbitration fees. Nothing in this Agreement shall prevent you or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

17. MISCELLANEOUS. This Agreement constitutes the complete, final and exclusive embodiment of the entire agreement between you and the Company with regard to its subject matter. It is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. This Agreement may not be modified or amended except in a writing signed by both you and a duly authorized officer of the Company. This Agreement will bind the heirs, personal representatives, successors and assigns of both you and the Company, and inure to the benefit of both you and the Company, their heirs, successors and assigns. If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination will not affect any other provision of this Agreement and the provision in question will be modified by the court so as to be rendered enforceable to the fullest extent permitted by law, consistent with the intent of the parties. This Agreement will be deemed to have been entered into and will be

construed and enforced in accordance with the laws of the State of California without regard to conflict of laws principles. Any ambiguity in this Agreement shall not be construed against either party as the drafter. Any waiver of a breach of this Agreement shall be in writing and shall not be deemed to be a waiver of any successive breach. This Agreement may be executed in counterparts and electronic or facsimile signatures will suffice as original signatures.

If this Agreement is acceptable to you, please sign below and return the original to me. You have 21 calendar days to decide whether to accept this Agreement, and the Company's offer contained herein will automatically expire if you do not sign and return it within that timeframe.

We wish you the best in your future endeavors.

Sincerely,

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

I HAVE READ, UNDERSTAND AND AGREE FULLY TO THE FOREGOING AGREEMENT:

/s/ Cyrus Harmon
Cyrus Harmon

3/21/2023
Date

Exhibit A

To be inserted by Cyrus and company reviewed/approved.

Exhibit 10.3

March 8, 2023

Kinney Horn
VIA EMAIL

Dear Kinney:

This letter sets forth the substance of the separation and consulting agreement (the "**Agreement**") that Olema Pharmaceuticals, Inc. (the "**Company**") is offering to you to aid in your employment transition.

1. SEPARATION. Your employment termination date will be March 24, 2023 (the "**Separation Date**").

2. ACCRUED SALARY. On the Separation Date, the Company will pay you all accrued salary earned through the Separation Date, subject to standard payroll deductions and withholdings. You are entitled to this payment by law. Because the Company has a nonaccrual vacation/PTO policy, you do not have any accrued vacation or other paid time off and thus will not be paid out for any accrued vacation or other paid time off.

3. SEVERANCE BENEFITS. If you timely sign this Agreement, allow it to become effective, and comply with your obligations under it, then the Company will provide you the following severance benefits:

(a) Severance Payment. The Company will pay you a lump-sum severance payment equal to (i) 12 months of your base salary in effect as of the Separation Date, plus (ii) your target bonus for 2023, pro-rated based on your months of service as an employee during 2023. This severance payment will be subject to standard payroll deductions and withholdings and paid no later than on the 60th day following the Separation Date.

(b) Health Insurance. To the extent provided by the federal COBRA law or, if applicable, state insurance laws, and by the Company's current group health insurance policies, you will be eligible to continue your group health insurance benefits at your own expense following the Separation Date. Later, you may be able to convert to an individual policy through the provider of the Company's health insurance, if you wish. You will be provided with a separate notice describing your rights and obligations under COBRA and a form for electing COBRA coverage. As an additional severance benefit under this Agreement, provided that you timely elect continued coverage under COBRA, then the Company will pay you a lump-sum amount of $20,825 which is equal to the COBRA premiums to continue your health insurance for one year following the Separation Date. This payment will be subject to standard payroll deductions and withholdings and paid with the severance payment under Section 3(a) above. You may, but are not required to, use this payment for health insurance premiums.

(c) Acceleration. You were granted a stock option on June 10, 2020 with respect to 252,060 shares of the Company's common stock (the "**Stock Option**"). The Company will accelerate the vesting of the Stock Option such that 50% of the unvested portion of the Stock Option as of the Separation Date (which equals 39,384 shares of common stock) shall be deemed vested and exercisable.

4. CONSULTING PERIOD. If you timely sign this Agreement, allow it to become effective, and comply with your obligations under it, then the Company will retain you as a consultant to the Company under the terms specified below.

(a) Term. The term of your consulting will commence on the Separation Date and continue until terminated with 30 days advance notice (the "**Consulting Period**").

(b) Consulting Services. During the Consulting Period, you will use your best efforts to provide consulting services as may be requested by the Company in any area of your experience (the "**Consulting Services**"). The Company anticipates that you will provide services at my request, and subject to my direction (or my designee), and anticipates that you will not be required to perform more than eight hours of service per week.

(c) Provision of Consulting Services. You agree to exercise the highest degree of professionalism and utilize your expertise and creative talents in performing the Consulting Services. You shall abide by the Company's applicable policies and procedures during the Consulting Period.

(d) Consulting Fees. During the Consulting Period, you will receive a consulting fee of $2,500 payable quarterly, commencing on April 1, 2023 ("**Consulting Fees**"). You shall seek advance written approval prior to incurring any expenses for which you will seek reimbursement in connection with your duties during the Consulting Period.

(e) Equity Awards. Because your service as an employee and consultant will be continuous, your termination of employment will not constitute a termination of service. Thus, vesting of your outstanding equity awards to acquire the Company's common stock (the "**Equity Awards**") will not cease as of the Separation Date but instead shall continue until your consulting services cease. Your Equity Awards shall continue to be governed by the plans under which they were granted and all applicable grant notices and agreements.

(f) Independent Contractor Relationship. During the Consulting Period, your relationship with the Company will be that of an independent contractor, and nothing in this Agreement is intended to, or should be construed to, create a partnership, agency, joint venture or employment relationship after the Separation Date. Except as expressly provided in this Agreement, you will not be entitled to, and will not receive, any benefits that the Company may make available to its employees, including but not limited to, group health or life insurance, profit-sharing or retirement benefits.

(g) Taxes and Withholding. As an independent contractor, the Company will not withhold any amount for taxes, social security or other payroll deductions relating to your

consulting service. The Company will issue you a Form 1099 with respect to any compensation resulting from your consulting service. Any taxable income resulting from your employment, including taxes upon exercise of nonqualified stock options or settlement of restricted stock units granted to you in your capacity as an employee, will be reported to you as employment income on Form W-2 and be subject to withholding that you will be required to satisfy to the extent required by law. You acknowledge that you will be entirely responsible for payment of any such taxes, and you hereby indemnify, defend and save harmless the Company, and its officers and directors in their individual capacity, from any liability for any taxes, penalties or interest that may be assessed by any taxing authority with respect to all compensation you receive under this Agreement, with the exception of the employer's share of social security, if any.

(h) Limitations on Authority. During the Consulting Period, you will have no responsibilities or authority as a consultant to the Company other than as provided above. You will have no authority to bind the Company to any contractual obligations, whether written, oral or implied, except with the prior written authorization of an officer of the Company. You agree not to represent or purport to represent the Company in any manner whatsoever to any third party unless authorized in advance by the Company, in writing, to do so.

(i) Confidential Information and Inventions. You agree that, during the Consulting Period and thereafter, you will not use or disclose, in any manner that is not authorized by the Company or essential to your performance of specifically requested Consulting Services, any confidential or proprietary information or materials of the Company that you obtain or develop in the course of performing the Consulting Services. Any and all work product you create in the course of performing the Consulting Services will be the sole and exclusive property of the Company. You hereby assign to the Company all right, title, and interest in all inventions, techniques, processes, materials, and other intellectual property developed in the course of performing the Consulting Services.

(j) Other Work Activities. Throughout the Consulting Period, you shall have the right to engage in employment, consulting, or other work relationships in addition to your work for the Company. The Company will make arrangements to enable you to perform your work for the Company at such times and in such a manner so that it will not unreasonably interfere with other activities in which you may engage. In order to protect the trade secrets and confidential and proprietary information of the Company, you agree that, during the Consulting Period, you will notify me in writing, and obtain the Company's written consent, before you obtain employment with, or perform competitive work for, any business entity that is competitive with the Company, or engage in any other work activity, or preparation for work activity, competitive with the Company.

(k) Termination of Consulting Period. Either party may terminate the Consulting Period upon 30 days' advance written notice to the other party. Additionally, the Company may terminate the Consulting Period immediately upon written notice to you in the event of your material breach of any legal or contractual obligation to the Company.

5. OTHER COMPENSATION OR BENEFITS. You acknowledge that, except as expressly provided in this Agreement, you have not earned and will not receive from the Company any additional compensation (including base salary, bonus, incentive compensation, or equity), severance, or benefits before or after the Separation Date, with the exception of any vested right you may have under the express terms of a written ERISA-qualified benefit plan (e.g., 401(k) account). You further acknowledge and agree that you are accepting the benefits set forth herein in full satisfaction of any severance benefits you are eligible to receive from the Company under any plan or agreement, including (without limitation) under the terms of your November 13, 2020 amended and restated offer letter with the Company.

6. EXPENSE REIMBURSEMENTS. You agree that, within 30 days after the Separation Date, you will submit your final documented expense reimbursement statement reflecting all business expenses you incurred through the Separation Date, if any, for which you seek reimbursement. The Company will reimburse you for these expenses pursuant to its regular business practice.

7. RELEASE OF CLAIMS.

(a) General Release of Claims. In exchange for the consideration provided to you under this Agreement to which you would not otherwise be entitled, you hereby generally and completely release the Company, and its affiliated, related, parent and subsidiary entities, and its and their current and former directors, officers, employees, shareholders, partners, agents, attorneys, predecessors, successors, insurers, affiliates, and assigns from any and all claims, liabilities, demands, causes of action, and obligations, both known and unknown, arising from or in any way related to events, acts, conduct, or omissions occurring at any time prior to and including the date you sign this Agreement.

(b) Scope of Release. This general release includes, but is not limited to: (i) all claims arising from or in any way related to your employment with the Company or the termination of that employment; (ii) all claims related to your compensation or benefits from the Company, including salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, or any other ownership, equity, or profits interests in the Company; (iii) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (iv) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (v) all federal, state, and local statutory claims, including claims for discrimination, harassment, retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964, the federal Americans with Disabilities Act of 1990, the California Labor Code, the California Family Rights Act, the Age Discrimination in Employment Act ("**ADEA**") and the California Fair Employment and Housing Act. **You acknowledge that you have been advised, as required by California Government Code Section 12964.5(b)(4), that you have the right to consult an attorney regarding this Agreement and that you were given a reasonable time period of not less than five business days in which to do so.** You further acknowledge and agree that, in the event you sign this Agreement prior to the end of the reasonable time period provided by the Company, your decision to accept such shortening of time is knowing and voluntary and is not induced by the Company

through fraud, misrepresentation, or a threat to withdraw or alter the offer prior to the expiration of the reasonable time period, or by providing different terms to employees who sign such an agreement prior to the expiration of the time period.

(c) ADEA Release. You acknowledge that you are knowingly and voluntarily waiving and releasing any rights you have under the ADEA, and that the consideration given for the waiver and releases you have given in this Agreement is in addition to anything of value to which you were already entitled. You further acknowledge that you have been advised, as required by the ADEA, that: (i) your waiver and release does not apply to any rights or claims arising after the date you sign this Agreement; (ii) you should consult with an attorney prior to signing this Agreement (although you may choose voluntarily not to do so); (iii) you have 21 days to consider this Agreement (although you may choose voluntarily to sign it sooner); (iv) you have seven days following the date you sign this Agreement to revoke this Agreement (in a written revocation sent to me); and (v) this Agreement will not be effective until the date upon which the revocation period has expired, which will be the eighth day after you sign this Agreement provided that you do not revoke it (the "**Effective Date**").

(d) Section 1542 Waiver. In giving the release herein, which includes claims that may be unknown to you at present, you acknowledge that you have read and understand Section 1542 of the California Civil Code, which reads as follows: **"A general release does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party."** You hereby expressly waive and relinquish all rights and benefits under that section and any law of any other jurisdiction of similar effect with respect to your release of claims herein, including but not limited to your release of unknown claims.

(e) Exceptions. Notwithstanding the foregoing, you are not releasing the Company hereby from: (i) any obligation to indemnify you pursuant to the Certificate of Incorporation and Bylaws of the Company, any valid fully executed indemnification agreement with the Company, applicable law, or applicable directors and officers liability insurance; (ii) any claims that cannot be waived by law; or (iii) any claims for breach of this Agreement.

(f) Protected Rights. You understand that nothing in this Agreement limits your ability to file a charge or complaint with the Equal Employment Opportunity Commission, the Department of Labor, the National Labor Relations Board, the Occupational Safety and Health Administration, the California Department of Fair Employment and Housing, the Securities and Exchange Commission or any other federal, state or local governmental agency or commission ("**Government Agencies**"). You further understand this Agreement does not limit your ability to communicate with any Government Agencies or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including providing documents or other information, without notice to the Company. While this Agreement does not limit your right to receive an award for information provided to the Securities and Exchange Commission, you understand and agree that, to maximum extent permitted by law, you are otherwise waiving any and all rights you may have to individual relief based on any claims that you have released and

any rights you have waived by signing this Agreement. Nothing in this Agreement (i) prevents you from discussing or disclosing information about unlawful acts in the workplace, such as harassment or discrimination or any other conduct that you have reason to believe is unlawful; or (ii) waives any rights you may have under Section 7 of the National Labor Relations Act (subject to the release of claims set forth herein).

8. RETURN OF COMPANY PROPERTY. You agree that, within ten days after each of the Separation Date and the Consulting Period, you will return to the Company all Company documents (and all copies thereof) and other Company property in your possession or control, including, but not limited to, Company files, notes, drawings, records, plans, forecasts, reports, studies, analyses, proposals, agreements, drafts, financial and operational information, research and development information, sales and marketing information, customer lists, prospect information, pipeline reports, sales reports, personnel information, specifications, code, software, databases, computer-recorded information, tangible property and equipment (including, but not limited to, computing and electronic devices, mobile telephones, servers), credit cards, entry cards, identification badges and keys; and any materials of any kind that contain or embody any proprietary or confidential information of the Company (and all reproductions or embodiments thereof in whole or in part).

9. CONFIDENTIAL INFORMATION OBLIGATIONS. You acknowledge and reaffirm your continuing obligations under your Employee Proprietary Information and Invention Assignment Agreement.

10. NON-DISPARAGEMENT. Except to the extent permitted by Section 7(f), you agree not to disparage the Company or its officers, directors, employees, shareholders, parents, subsidiaries, affiliates, and agents, in any manner likely to be harmful to its or their business, business reputation, or personal reputation; provided that you may respond accurately and fully to any request for information if required by legal process or in connection with a government investigation. In addition, nothing in this provision or this Agreement prohibits or restrains you from making disclosures protected under the whistleblower provisions of federal or state law, or from exercising your rights to engage in protected speech under Section 7 of the National Labor Relations Act, if applicable

11. NO VOLUNTARY ADVERSE ACTION. You agree that you will not voluntarily (except in response to legal compulsion or as permitted under the section of this Agreement entitled "**Protected Rights**") assist any person in bringing or pursuing any proposed or pending litigation, arbitration, administrative claim or other formal proceeding against the Company, its parent or subsidiary entities, affiliates, officers, directors, employees or agents.

12. COOPERATION. You agree to cooperate fully with the Company in connection with its actual or contemplated defense, prosecution, or investigation of any claims or demands by or against third parties, or other matters arising from events, acts, or failures to act that occurred during the period of your employment by the Company. Such cooperation includes, without limitation, making yourself available to the Company upon reasonable notice, without subpoena, to provide complete, truthful and accurate information in witness interviews, depositions, and trial

testimony. The Company will reimburse you for reasonable out-of-pocket expenses you incur in connection with any such cooperation (excluding foregone wages) and will make reasonable efforts to accommodate your scheduling needs.

13. NO ADMISSIONS. You understand and agree that the promises and payments in consideration of this Agreement shall not be construed to be an admission of any liability or obligation by the Company to you or to any other person, and that the Company makes no such admission.

14. REPRESENTATIONS. You hereby represent that you have: been paid all compensation owed and for all hours worked; received all leave and leave benefits and protections for which you are eligible pursuant to the Family and Medical Leave Act, the California Family Rights Act, or otherwise; and not suffered any on-the-job injury for which you have not already filed a workers' compensation claim.

15. DISPUTE RESOLUTION. You and the Company agree that any and all disputes, claims, or controversies of any nature whatsoever arising from, or relating to, this Agreement or its interpretation, enforcement, breach, performance or execution, your employment or the termination of such employment (including, but not limited to, any statutory claims), shall be resolved, pursuant to the Federal Arbitration Act, 9 U.S.C. §1-16, and to the fullest extent permitted by law, by final, binding and confidential arbitration in San Francisco, California (or another mutually acceptable location) conducted before a single neutral arbitrator by JAMS, Inc. ("**JAMS**") or its successor, under the then applicable JAMS Arbitration Rules and Procedures for Employment Disputes (available at http://www.jamsadr.com/rules-employment-arbitration/). **By agreeing to this arbitration procedure, both you and the Company waive the right to have any claim resolved through a trial by jury or judge.** You will have the right to be represented by legal counsel at any arbitration proceeding, at your own expense. This paragraph shall not apply to any action or claim that cannot be subject to mandatory arbitration as a matter of law, to the extent such claims are not permitted by applicable law to be submitted to mandatory arbitration and the applicable law(s) are not preempted by the Federal Arbitration Act or otherwise invalid (collectively, the "**Excluded Claims**"). In the event you intend to bring multiple claims, including one of the Excluded Claims listed above, the Excluded Claims may be publicly filed with a court, while any other claims will remain subject to mandatory arbitration. The arbitrator shall have sole authority for determining if a claim is subject to arbitration, and any other procedural questions related to the dispute and bearing on the final disposition. In addition, the arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be available under applicable law in a court proceeding; and (b) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The Company shall pay all JAMS arbitration fees. Nothing in this Agreement shall prevent you or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

16. MISCELLANEOUS. This Agreement constitutes the complete, final and exclusive embodiment of the entire agreement between you and the Company with regard to its subject matter. It is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. This Agreement may not be modified or amended except in a writing signed by both you and a duly authorized officer of the Company. This Agreement will bind the heirs, personal representatives, successors and assigns of both you and the Company, and inure to the benefit of both you and the Company, their heirs, successors and assigns. If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination will not affect any other provision of this Agreement and the provision in question will be modified by the court so as to be rendered enforceable to the fullest extent permitted by law, consistent with the intent of the parties. This Agreement will be deemed to have been entered into and will be construed and enforced in accordance with the laws of the State of California without regard to conflict of laws principles. Any ambiguity in this Agreement shall not be construed against either party as the drafter. Any waiver of a breach of this Agreement shall be in writing and shall not be deemed to be a waiver of any successive breach. This Agreement may be executed in counterparts and electronic or facsimile signatures will suffice as original signatures.

If this Agreement is acceptable to you, please sign below and return the original to me. You have 21 calendar days to decide whether to accept this Agreement, and the Company's offer contained herein will automatically expire if you do not sign and return it within that timeframe.

We wish you the best in your future endeavors.

Sincerely,

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

I HAVE READ, UNDERSTAND AND AGREE FULLY TO THE FOREGOING AGREEMENT:

/s/ Kinney Horn
Kinney Horn

March 8, 2023
Date

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: May 9, 2023

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: May 9, 2023

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

Exhibit 32.1

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

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

(1) The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2023, 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: May 9, 2023

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

Date: May 9, 2023

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."