UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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 001-36500

CymaBay Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**94-3103561**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
7575 Gateway Blvd, Suite 110 Newark, CA	**94560**
(Address of principal executive offices)	**(Zip Code)**

(510) 293-8800
(Registrant's telephone number, including area code)

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, $0.0001 par value per share	CBAY	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, anon-accelerated filer, a 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 April 30, 2023, there were 97,513,179 shares of the registrant's common stock outstanding.

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CYMABAY THERAPEUTICS, INC.
QUARTERLY REPORT ON FORM 10-Q

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

CymaBay Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)
(unaudited)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 59,150	$ 20,291
Marketable securities	177,215	115,194
Prepaid expenses and other current assets	6,355	2,588
Total current assets	242,720	138,073
Property and equipment, net	729	701
Operating lease right-of-use asset	137	169
Other assets	1,733	2,909
Total assets	$ 245,319	$ 141,852
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,633	$ 1,096
Accrued research and development expenses	5,565	6,530
Deferred collaboration revenue	33,733	—
Other accrued liabilities	5,569	7,815
Total current liabilities	46,500	15,441
Development financing liability	94,630	90,227
Long-term portion of operating lease liability	—	30
Total liabilities	141,130	105,698
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value: 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.0001 par value: 200,000,000 shares authorized; 97,330,560 and 84,681,063 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	17	8
Additional paid-in capital	1,005,877	909,329
Accumulated other comprehensive loss	(70)	(326)
Accumulated deficit	(901,635)	(872,857)
Total stockholders' equity	104,189	36,154
Total liabilities and stockholders' equity	$ 245,319	$ 141,852

See accompanying notes to the condensed consolidated financial statements.

CymaBay Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share information)
(unaudited)

	Three Months Ended March 31,	
	2023	2022
Operating expenses:		
Research and development	$ 18,551	$ 18,415
General and administrative	8,324	6,087
Total operating expenses	26,875	24,502
Loss from operations	(26,875)	(24,502)
Other income (expense), net:		
Interest income	2,013	98
Interest expense	(4,403)	(3,365)
Other income	487	—
Total other income (expense), net	(1,903)	(3,267)
Net loss	$ (28,778)	$ (27,769)
Other comprehensive loss:		
Unrealized gain (loss) on marketable securities, net of tax	256	(206)
Total other comprehensive loss	256	(206)
Comprehensive loss	$ (28,522)	$ (27,975)
Basic and diluted net loss per common share	$ (0.29)	$ (0.32)
Weighted average common shares outstanding used to calculate basic and diluted net loss per common share	97,971,081	87,802,939

See accompanying notes to the condensed consolidated financial statements.

CymaBay Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(unaudited)

	Three Months Ended March 31,	
	2023	2022
Operating activities		
Net loss	$ (28,778)	$ (27,769)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	199	169
Stock-based compensation expense	3,487	2,414
Accretion of development financing liability	4,403	3,365
Net accretion and amortization of investments in marketable securities	(1,318)	131
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(3,767)	1,077
Other assets	1,176	(728)
Accounts payable	537	(2,341)
Deferred collaboration revenue	33,733	—
Accrued research and development expenses	(965)	(93)
Other accrued liabilities	(2,276)	(1,587)
Net cash provided by (used in) operating activities	6,431	(25,362)
Investing activities		
Purchases of property and equipment	(195)	—
Purchases of marketable securities	(121,097)	(62,485)
Proceeds from maturities of marketable securities	60,650	11,495
Net cash (used in) investing activities	(60,642)	(50,990)
Financing activities		
Proceeds from issuance of common stock pursuant to equity award plans	710	—
Proceeds from issuance of common stock andpre-funded warrants, net of issuance costs	92,360	(459)
Proceeds from development financing	—	25,000
Net cash provided by financing activities	93,070	24,541
Net increase (decrease) in cash and cash equivalents	38,859	(51,811)
Cash and cash equivalents at beginning of period	20,291	125,806
Cash and cash equivalents at end of period	$ 59,150	$ 73,995
Supplemental disclosure		
Cash paid for amounts included in the measurement of lease liabilities	$ 176	$ 171

See accompanying notes to the condensed consolidated financial statements.

CymaBay Therapeutics, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(In thousands, except share information)
(unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances as of December 31, 2022	84,681,063	$ 8	$ 909,329	$ (326)	$ (872,857)	$ 36,154
Issuance of common stock upon exercise of options and awards	203,077	—	710	—	—	710
Issuance of common stock and pre-funded warrants, net of $5,390 issuance costs	11,821,428	9	92,351	—	—	92,360
Exercise of pre-funded warrants	624,992	—	—	—	—	—
Stock-based compensation expense	—	—	3,487	—	—	3,487
Net loss	—	—	—	—	(28,778)	(28,778)
Net unrealized gain on marketable securities	—	—	—	256	—	256
Balances as of March 31, 2023	97,330,560	$ 17	$1,005,877	$ (70)	$ (901,635)	$ 104,189

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances as of December 31, 2021	84,677,939	$ 8	$899,798	$ (13)	$ (766,856)	$ 132,937
Issuance costs related to issuance of common stock and pre-funded warrants	—	—	5	—	—	5
Stock-based compensation expense	—	—	2,414	—	—	2,414
Net loss	—	—	—	—	(27,769)	(27,769)
Net unrealized loss on marketable securities	—	—	—	(206)	—	(206)
Balances as of March 31, 2022	84,677,939	$ 8	$902,217	$ (219)	$ (794,625)	$ 107,381

See accompanying notes to the condensed consolidated financial statements.

CymaBay Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Organization and Description of Business

CymaBay Therapeutics, Inc. (the Company or CymaBay) is a clinical-stage biopharmaceutical company focused on developing and providing access to innovative therapies for patients with liver and other chronic diseases with high unmet medical need. The Company's key clinical development candidate is seladelpar. Seladelpar has been under development primarily for the treatment of primary biliary cholangitis (PBC), a rare liver disease. The Company was incorporated in Delaware in October 1988 as Transtech Corporation. The Company's headquarters and operations are located in Newark, California and it operates in one segment.

Liquidity

The Company has incurred net operating losses and negative cash flows from operations since its inception. During the three months ended March 31, 2023, the Company incurred a net loss of $28.8 million and generated $6.4 million of net cash flow from operations. At March 31, 2023, the Company had an accumulated deficit of $901.6 million.

Historically, the Company has incurred substantial research and development expenses in the course of studying its product candidates in clinical trials. To date, none of the Company's product candidates have been approved for marketing and sale, and the Company has not recorded any revenue from product sales. Generally, the Company's ability to achieve profitability is dependent on its ability to successfully develop, acquire or in-license additional product candidates, conduct clinical trials for those product candidates, obtain regulatory approvals, and support commercialization activities for those product candidates. Any products developed will require approval of the U.S. Food and Drug Administration (FDA) or a foreign regulatory authority prior to commercial sale. The regulatory approval process is expensive, time-consuming, and uncertain, and any denial or delay of approval could have a material adverse effect on the Company. Even if approved, the Company's products may not achieve market acceptance and will face competition from both generic and branded pharmaceutical products.

As of March 31, 2023, the Company had cash, cash equivalents and marketable securities totaling $236.4 million, which the Company believes is sufficient to fund its current operating plan for at least twelve months from the issuance date of its financial statements. The Company has historically obtained, and expects to obtain in the future, additional financing to fund its business strategy through: future equity offerings; debt financing; one or more possible licenses, collaborations or other similar arrangements with respect to development and/or commercialization rights of the Company's product candidates; or a combination of the above. It is unclear if or when any such transactions will occur, on satisfactory terms or at all. The Company's failure to raise capital as and when needed could have a negative impact on its financial condition and its ability to pursue its business strategies. If adequate funds are not available to the Company, it could have a material adverse effect on the Company's business, results of operations, and financial condition. Market volatility could also adversely impact the Company's investments as well as its ability to access capital when and as needed. Failure to raise sufficient capital when needed could require the Company to significantly delay, scale back or discontinue one or more of its product development programs or commercialization efforts, or other aspects of its business plans, and the Company's operating results and financial condition would be adversely affected.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying interim condensed consolidated financial statements are unaudited and are comprised of the accounts of CymaBay and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. The Company has no unconsolidated subsidiaries or investments accounted for under the equity method.

These unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP), which requires management to make informed estimates and assumptions that impact the amounts and disclosures reported in the condensed consolidated financial statements and accompanying notes, and the requirements of the United States Securities and Exchange Commission (SEC) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted.

In management's opinion, the unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited financial statements and include normal recurring adjustments necessary for the fair presentation of the Company's financial position and its results of operations and comprehensive loss and its cash flows for the periods presented. These statements do not include all disclosures required by U.S. GAAP and should be read in conjunction with the Company's financial statements and accompanying notes for the fiscal year ended December 31, 2022, which is contained in the Company's Annual Report on Form 10-K as filed with the SEC on March 23, 2023. The results for the three months ended March 31, 2023 are not necessarily indicative of results to be expected for the entire year ending December 31, 2023 or future operating periods.

The condensed consolidated financial statements have been prepared in accordance with U.S. GAAP, which requires management to make estimates and assumptions that affect the amounts and disclosures reported in the condensed consolidated financial statements and accompanying notes. Management bases its estimates on historical experience and on assumptions believed to be reasonable under the circumstances. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes, and management must select an amount that falls within that range of reasonable estimates. Actual results could differ materially from those estimates and assumptions. These estimates form the basis for making judgments about the carrying values of assets and liabilities when these values are not readily apparent from other sources. Estimates are assessed each reporting period and updated to reflect current information and any changes in estimates will generally be reflected in the period first identified.

Revenue Recognition

As part of the Company's drug development strategy, the Company periodically enters into collaboration arrangements with third party collaborators, under which the Company may license certain rights to our intellectual property to permit collaborators to further develop, manufacture and/or otherwise commercialize its drug candidates. The terms of these agreements typically include, but are not limited to, payments to the Company of one or more of the following: nonrefundable, upfront license fees; development and commercial milestone payments whose payment is typically contingent upon milestone achievement; funding of research and/or development activities; and royalties on net sales of licensed products.

At the inception of an arrangement, the Company evaluates if a counterparty to a contract is a customer, if the arrangement is within the scope of *ASC 606—Revenue from Contracts with Customers*, and the term of the contract. The Company recognizes revenue when the customer obtains control of promised goods or services in a contract for an amount that reflects the consideration the Company expects to receive in exchange for those goods or services. For contracts with customers, the Company applies the following five-step model in order to determine this amount: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including any constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. As part of the accounting for contracts with customers, the Company must develop assumptions that require judgment to determine the standalone selling price of each performance obligation identified in the contract. The Company then allocates the total transaction price to each performance obligation based on the estimated standalone selling prices of each performance obligation. The Company recognizes the amount of the transaction price allocated to the respective performance obligation as revenue when the performance obligation is satisfied or as it is satisfied.

Upfront License Fees: If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from nonrefundable, upfront license fees allocated to the license at a point in time when the license is effective and the underlying intellectual property has been made available to the collaborator and the collaborator is able to use and benefit from the license. For licenses that are not distinct from other promised goods and services, as well as for other performance obligations identified in the arrangement, the Company utilizes judgment to assess the nature of the performance obligation to determine whether it is satisfied over time or at a point in time. A performance obligation is satisfied over time if the customer simultaneously receives and consumes the benefits from the Company's performance, if the Company's performance enhances an asset controlled by the customer, or if the Company has an enforceable right to be paid by the customer and the Company's performance does not create an asset that has alternative use to the Company.

If a performance obligation is satisfied over time, the Company applies an appropriate method of measuring progress for purposes of recognizing revenue from nonrefundable, upfront license fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

The selection of the method to measure progress towards completion requires judgment and is based on the nature of the products or services to be provided. Revenue is recorded proportionally to the selected measure of progress either over the service period or at a point in time based on the products or services to be provided. The Company uses the cost-to-cost measure of progress when it best depicts the transfer of control to the customer which occurs as the Company incurs costs. Under the cost-to-cost measure of progress, the extent of progress towards completion is measured based on the ratio of costs incurred to date to the total estimated costs at completion of the performance obligation (an "input method" under Topic 606). The Company uses judgment to estimate the total cost expected to complete the research and development performance obligations, which include subcontractors' costs, labor, materials, other direct costs and an allocation of indirect costs. The Company evaluates these cost estimates and the progress each reporting period and, as necessary, it adjusts the measure of progress and related revenue recognition.

If the arrangement includes optional goods and services, the Company assesses whether delivery of such goods and services requires the customer to pay fees consistent with their standalone selling prices, or if customer may be entitled to incremental discounts that it would not have received without entering into the agreement and committing to purchase the initial goods and services. Presence of such discounts indicates the customer has received material rights which also represent performance obligations.

Development and Regulatory Milestone Payments: Depending on facts and circumstances, the Company may conclude that it is appropriate to include a milestone payment in the estimated transaction price using the most likely amount method or that it is appropriate to fully constrain the milestone. A milestone payment is included in the transaction price in the reporting period when the Company concludes that it is probable that recording revenue in the period will not result in a significant reversal of revenue in future periods. The Company may record revenues from certain milestones in a reporting period before the milestone is achieved if it concludes that achievement of the milestone is probable and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods. Revenue from milestones is recognized to the extent of progress made in satisfying the associated performance obligation(s). The Company records a corresponding contract asset when this conclusion is reached. Milestone payments that have not been included in the transaction price to date are fully constrained. These milestones remain fully constrained until the Company concludes that achievement of the milestone is probable and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods. The Company re-evaluates the probability of achievement of such development and regulatory milestones and any related constraint each reporting period. The Company adjusts our estimate of the overall transaction price, including the amount of licensing revenue that was recorded, if necessary.

Sales-based Milestone and Royalty Payments: The Company's collaborators may be required to pay it sales-based milestone payments or royalties on future sales of commercial products. The Company recognize revenues related to sales-based milestone and royalty payments upon the later to occur of (i) achievement of the collaborator's underlying sales or (ii) satisfaction of any performance obligation(s) related to these sales, in each case provided that the license to our intellectual property is deemed to be the predominant item to which the sales-based milestones and/or royalties relate.

The Company receives payments from its customers based on billing schedules established in each contract. Upfront payments and fees are recorded as deferred revenue upon receipt or when due until the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

The Company allocates amounts included in the transaction price based on standalone selling prices of various performance obligations. Variable consideration (such as milestones and royalties) is allocated to specific performance obligations if it is triggered through our performance or represents a specific outcome from the performance associated with this performance obligation, and if such allocation would meet the allocation objective of allocating to each performance obligation an amount that depicts consideration to which the Company would be entitled in exchange for delivery of such performance obligation. The remaining consideration is generally allocated on a relative standalone selling price basis.

The Company determines standalone selling prices using a variety of methods, including cost associated with our performance plus a reasonable margin, prices observed in the market for similar goods or services, and valuation techniques involving projected discounted cash flows.

Fair Value of Financial Instruments

The Company's financial instruments during the periods reported consist of cash, cash equivalents, marketable securities, accounts payable, certain accrued liabilities, and the development financing liability.

Fair value is defined 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 at the measurement date. Assets and liabilities that are measured at fair value are reported using a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. This hierarchy maximizes the use of observable inputs and minimizes the use of unobservable inputs and is as follows:

Level 1—Quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2—Inputs other than quoted prices in active markets that are observable for the asset or liability, either directly or indirectly.

Level 3—Inputs that are significant to the fair value measurement and are unobservable (i.e. supported by little or no market activity), which requires the reporting entity to develop its own valuation techniques and assumptions.

The carrying amounts of cash equivalents approximate their related fair values due to the short-term nature of these instruments. Cash equivalents are classified as level 1 and accounts payable and accrued liabilities as level 2 under the fair value hierarchy.

The following tables present the Company's financial assets that are measured at fair value on a recurring basis using the above input categories (in thousands):

	As of March 31, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$57,843	$ —	$ —	$ 57,843
Total cash equivalents	57,843	—	—	57,843
Marketable securities:				
U.S. and foreign commercial paper	—	85,120	—	85,120
U.S. and foreign corporate debt securities	—	10,375	—	10,375
Supranational debt securities	—	4,475	—	4,475
U.S. agency securities	—	26,159	—	26,159
U.S. treasury securities	—	51,086	—	51,086
Total marketable securities	—	177,215	—	177,215
Total assets measured at fair value	$57,843	$177,215	$ —	$235,058

	As of December 31, 2022			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$9,770	$ —	$ —	$ 9,770
Total cash equivalents	9,770	—	—	9,770
Marketable securities:				
U.S. and foreign commercial paper	—	46,121	—	46,121
U.S. and foreign corporate debt securities	—	24,807	—	24,807
Supranational debt securities	—	12,890	—	12,890
U.S. agency securities	—	7,759	—	7,759
U.S. treasury securities	—	23,617	—	23,617
Total marketable securities	—	115,194	—	115,194
Total assets measured at fair value	$9,770	$115,194	$ —	$124,964

The Company estimates the fair value of its money market funds, corporate debt, asset-backed securities, commercial paper, U.S. treasury securities, U.S agency securities, and supranational debt securities by taking into consideration data obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities, prepayment/default projections based on historical data, and other observable inputs.

The fair value of the Company's development financing liability is $85.1 million. The development financing liability is classified as level 3 under the fair value hierarchy, as its valuation is based on a discounted cash flow model that uses unobservable inputs such as the estimated timing of regulatory approval, attainment of certain sales milestones and the discount rate.

Cash, Cash Equivalents, and Marketable Securities

The Company considers all highly liquid investments with an original maturity of90 days or less at the time of purchase to be cash equivalents. Cash and cash equivalents consist of deposits with commercial banks in checking, interest-bearing, and money market funds.

The Company invests excess cash in marketable securities with high credit ratings. These securities consist primarily of corporate debt, commercial paper, asset-backed securities, U.S. treasury securities, and supranational debt securities and are classified as “available-for-sale.” The Company considers marketable securities as short-term investments if the maturity date is less than or equal to one year from the balance sheet date. The Company considers marketable securities as long-term investments if the maturity date is in excess of one year from the balance sheet date.

Realized gains and losses from the sale of marketable securities, if any, are calculated using the specific-identification method. Expected losses judged to be related partially or in whole to declines in credit risk-related factors of the security issuer are included in interest income or expense in the condensed consolidated statements of operations and comprehensive loss at the time the factors contributing to the expected losses are identified. Unrealized holding gains and losses are reported in accumulated other comprehensive loss in the condensed consolidated balance sheets. To date, the Company has not recorded any expected losses on its marketable securities related to credit risk-related declines in market value. In determining whether a decline in market value is related to expected credit losses, various factors are considered, including the cause, duration of time and severity of the expected loss, any adverse changes in the investees’ financial condition, and the Company’s intent and ability to hold the security for a period of time sufficient to allow for an anticipated recovery in market value.

Unrealized gains and losses of the Company's available-for-sale marketable securities as of March 31, 2023 and December 31, 2022 are presented in the tables below (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
As of March 31, 2023:				
Cash equivalents:				
Money market funds	$ 57,843	$ —	$ —	$ 57,843
Total cash equivalents	57,843	—	—	57,843
Current marketable securities:				
U.S. and foreign commercial paper	85,120	—	—	85,120
U.S. and foreign corporate debt securities	10,449	—	(74)	10,375
Supranational debt securities	4,489	—	(14)	4,475
U.S. agency securities	26,143	37	(21)	26,159
U.S. treasury securities	51,084	48	(46)	51,086
Total current marketable securities	177,285	85	(155)	177,215
Total marketable securities	$235,128	$ 85	$ (155)	$235,058

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
As of December 31, 2022:				
Cash equivalents:				
Money market funds	$ 9,770	$ —	$ —	$ 9,770
Total cash equivalents	9,770	—	—	9,770
Current marketable securities:				
U.S. and foreign commercial paper	46,121	—	—	46,121
U.S. and foreign corporate debt securities	24,964	—	(157)	24,807
Supranational debt securities	12,946	—	(56)	12,890
U.S. agency securities	7,782	16	(39)	7,759
U.S. treasury securities	23,707	2	(92)	23,617
Total current marketable securities	115,520	18	(344)	115,194
Total marketable securities	$125,290	$ 18	$ (344)	$124,964

The following table shows the fair value of the Company's marketable securities, by contractual maturity, as of March 31, 2023 (in thousands):

Due less than 1 year	$177,215
Due between 1 and 2 years	—
Total fair value	$177,215

Concentration of Risk

Cash, cash equivalents, and marketable securities consist of financial instruments that potentially subject the Company to a concentration of credit risk to the extent of the fair value recorded on the balance sheet. The Company invests cash that is not required for immediate operating needs primarily in highly liquid instruments that bear minimal risk. The Company has established guidelines relating to the quality, diversification, and maturities of securities to enable the Company to manage its credit risk. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash, cash equivalents and investments and issuers of investments to the extent recorded on the condensed consolidated balance sheets.

Certain materials and key components that the Company utilizes in its operations are obtained through single suppliers. Since the suppliers of key components and materials must be named in a new drug application NDA filed with the FDA for a product, significant delays can occur if the qualification of a new supplier is required. If delivery of material from the Company's suppliers were interrupted for any reason, the Company may be unable to supply any of its product candidates for clinical trials.

Research and Development Expenses

Research and development expenses consist of costs incurred in identifying, developing, and testing product candidates. These expenses consist primarily of costs for research and development personnel, including related stock-based compensation; contract research organizations (CRO) and other third parties that assist in managing, monitoring, and analyzing clinical trials; investigator and site fees; laboratory services; consultants; contract manufacturing services; non-clinical studies, including materials; and allocated expenses, such as depreciation of assets, and facilities and information technology that support research and development activities. Research and development costs are expensed as incurred, including expenses that may or may not be reimbursed under research and development funding arrangements. Payments made prior to the receipt of goods or services to be used in research and development are recorded as prepaid assets until the goods are received or services are rendered. Such payments are evaluated for current or long-term classification based on when they will be realized. Additionally, if expectations change such that the Company does not expect goods to be delivered or services to be rendered, such prepayments are charged to expense.

The Company records expenses related to clinical studies and manufacturing development activities based on its estimates of the services received and efforts expended pursuant to contracts with multiple CROs and manufacturing vendors that conduct and manage these activities on its behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows. There may be instances in which payments made to the Company's vendors will exceed the level of services provided and result in a prepayment. Payments under some of these contracts depend on factors such as the successful enrollment of subjects and the completion of clinical trial milestones. In amortizing or accruing service fees, the Company estimates the time period over which services will be performed, enrollment of subjects, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the Company's estimate, the Company will adjust the accrued or prepaid expense balance accordingly. To date, there have been no material differences from the Company's estimates to the amounts actually incurred.

Development Financing Agreement

The Company accounts for the Financing Agreement (see Note 4) as a debt instrument. Accordingly, the Company has recorded payments received under the Financing Agreement as part of a development financing liability in the Company's condensed consolidated balance sheet. The liability is recorded at amortized cost and accreted to the contractual success fee amounts based on the estimated timing of regulatory approval and attainment of certain sales milestones using an imputed interest rate. Certain transaction fees incurred specifically to complete the Financing Agreement were capitalized and recorded as a reduction to the carrying amount of the development financing liability and are being amortized to interest expense using the effective interest rate method.

There are several factors that could affect the estimated timing of regulatory approval and attainment of sales milestones, some of which are not entirely within the Company's control. Therefore, at each reporting date, the Company reassesses the estimated timing of regulatory approval and attainment of sales milestones and the expected contractual success fee payments due therefrom. If the timing and/or amount of such expected payments is materially different than original estimates, the Company will prospectively adjust the accretion of the development financing liability and the imputed interest rate.

The Company identified certain contingent repayment features in the Financing Agreement that are required to be bifurcated from the debt host instrument as embedded derivative liabilities; however, the Company determined the fair value of these features, both individually and in the aggregate, was immaterial at inception and as of March 31, 2023. The fair value of these features will be assessed at each reporting date and will be marked to market, if material. To determine the amount to record for the embedded derivative liabilities, the Company must assess the probability of occurrence of various potential future events that could affect the timing and/or amount of future cash flows related to the Financing Agreement.

Stock-Based Compensation

Stock-based compensation is measured at fair value on the grant date of the award. Compensation cost is recognized as expense on a straight-line basis over the vesting period for options with service conditions, and forfeitures are accounted for as they occur. The Company uses the Black-Scholes option pricing model to determine the fair value of stock option awards. The determination of fair value for stock-based awards using an option-pricing model requires management to make certain assumptions regarding subjective input variables such as expected term, dividends, volatility and risk-free rate. If actual results are not consistent with the Company's assumptions and judgments used in making these estimates, the Company may be required to increase or decrease compensation expense, which could be material to the Company's results of operations.

Recently Issued Accounting Pronouncements

ASU 2016-13

In June 2016, the FASB issued ASUNo. 2016-13, Financial Instruments—Credit Losses (Topic 326):*Measurement of Credit Losses on Financial Instruments*, an amendment which modifies the measurement and recognition of credit losses for most financial assets and certain other instruments. The amendment updates the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the "incurred loss" model with an "expected loss" model. Accordingly, these financial assets will be presented at the net amount expected to be collected. The amendment also requires that credit losses related to available-for-sale debt securities be recorded as an allowance through net income rather than reducing the carrying amount under the current, other-than-temporary-impairment model. In November 2019, FASB issued ASU No. 2019-10, Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815) and Leases (Topic 842), which deferred the adoption deadline for smaller reporting companies to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted, and entities are required to use a modified retrospective approach, with certain exceptions. The Company adopted this standard on January 1, 2023 and noted no material impact on its condensed consolidated financial statements and related disclosures.

3. Other Accrued Liabilities

Other accrued liabilities consist of (in thousands):

	March 31, 2023	December 31, 2022
Accrued compensation	$ 2,299	$ 5,779
Accrued professional fees and other	2,733	1,372
Current portion of operating lease liability	537	664
Total other accrued liabilities	$ 5,569	$ 7,815

4. Development Financing Agreement

On July 30, 2021 (the Effective Date), the Company entered into a Development Financing Agreement (the Financing Agreement) with an affiliate of Abingworth LLP (Abingworth) to provide funding to the Company to support its development of seladelpar for the treatment of primary biliary cholangitis (PBC). The Financing Agreement provided the Company $75.0 million in base funding, of which $25.0 million was provided in August 2021, $25.0 million was provided in November 2021, and $25.0 million was provided in January 2022. The use of proceeds from the funding is limited to PBC "Development Program" costs incurred or paid as defined in the Financing Agreement. In return, the Company will pay to Abingworth:

(1) contingent upon the first to occur of regulatory approval of seladelpar for the treatment of PBC in the U.S., U.K., Germany, Spain, Italy or France (Regulatory Approval), fixed success payments equal to 2.0x of the funding provided, consisting of $10 million payable in 90 days after the Regulatory Approval and thereafter, payments due on the first six anniversaries of the Regulatory Approval in the amounts of $15.0 million, $22.5 million, $22.5 million, $25.0 million, $27.5 million and $27.5 million, respectively and

(2) variable success payments equal to 1.1x of the funding provided, consisting of sales milestone payments of (x) $17.5 million and $27.5 million, respectively upon first reaching certain cumulative U.S. product sales thresholds, and (y) $37.5 million upon first reaching a specified U.S. product sales run rate.

Promptly following receipt of Regulatory Approval, the Company is required to execute a note agreement and deliver a promissory note to Abingworth within two business days to convert the fixed and variable success payments into a note payable. At the time that Abingworth receives, collectively, an aggregate of 3.1x of the funding provided ($232.5 million), the Company's payment obligations under the Financing Agreement will be fully satisfied. The Company has the option to satisfy its payment obligations to Abingworth upon Regulatory Approval, or a change of control of the Company, by paying an amount equal to the remaining payments payable to Abingworth subject to a mid-single-digit discount rate. Upon a change of control of the Company, an acceleration payment of 1.35x of the funding provided is payable, net of payments already made to Abingworth and creditable against future payments to Abingworth.

Pursuant to the Financing Agreement, the Company granted Abingworth a security interest in all its assets (other than intellectual property not related to seladelpar), provided that the Company is permitted to incur certain indebtedness. The security interest will terminate when the Company has paid Abingworth 2.0x of the funding provided or upon certain terminations of the Financing Agreement.

The Financing Agreement provides for negative, affirmative and additional covenants, which the Company must comply with for the duration of the Financing Agreement term. As of March 31, 2023, the Company was in compliance with all covenants stipulated in the Financing Agreement.

In certain instances, upon the termination of the Financing Agreement, the Company will be obligated to pay Abingworth a multiple of the amounts paid to the Company under the Financing Agreement, including specifically:

(i) 310% of such amounts in the event that Abingworth terminates the Financing Agreement due to (x) a Fundamental Breach, as defined in the Financing Agreement, (y) the bankruptcy of the Company, or (z) a safety concern resulting from gross negligence on the part of the Company or due to a safety concern that was material on the Effective Date and the material data showing such safety concern was not publicly known, disclosed to Abingworth, or in the diligence room made available to Abingworth,

(ii) 200% of such amounts in the event the Financing Agreement is terminated due to (x) Material Breach, as defined in the Financing Agreement, by the Company or (y) the security interests of Abingworth being invalidated or terminated other than as set forth in the Financing Agreement, and

(iii) 100% of such amounts in the event of certain irresolvable disagreements within the executive review committee overseeing the Company's development of seladelpar.

In addition, if, following certain terminations, the Company continues to develop seladelpar for the treatment of PBC and obtains regulatory approval, it will make the payments to Abingworth as if the Financing Agreement had not been terminated, less any payments made upon termination.

The Company shall not be obligated to make any payments to Abingworth under certain instances of technical or regulatory failure of the PBC development program as defined in the Financing Agreement.

As part of the arrangement, an executive review committee was established between the Company and Abingworth to discuss the Company's development of seladelpar.

The Company evaluated the Financing Agreement and determined it to be a research and development funding arrangement with the characteristics of a debt instrument, as the transfer of financial risk to Abingworth was not considered substantive and genuine. Accordingly, the Company has recorded payments received under the Financing Agreement as part of a development financing liability in its condensed consolidated balance sheets. The Company accounts for the overall development financing liability at amortized cost based on the estimated timing of regulatory approval and attainment of certain sales milestones and the contractual success fee payments expected to be due therefrom, as discounted using an imputed interest rate. The development financing liability is being accreted as interest expense to its expected future repayment amount over the expected life of the agreement using the effective interest rate method. Certain legal and financial advisory fees incurred specifically to complete the Financing Agreement were capitalized and recorded as a reduction to the carrying amount of the development financing liability and are also being amortized to interest expense using the effective interest method.

There are several factors that could affect the estimated timing of regulatory approval and attainment of sales milestones, some of which are not entirely within the Company's control. Therefore, the Company periodically reassesses the estimated timing of regulatory approval and attainment of sales milestones and the expected contractual success fee payments due therefrom. If the timing and/or amount of such expected payments is materially different than original estimates, the Company will prospectively adjust the accretion of the development financing liability and the imputed interest rate.

The Company identified certain contingent repayment features in the agreement that are required to be bifurcated from the debt host instrument as embedded derivative liabilities; however, the fair value of these features was immaterial at the Effective Date and as of March 31, 2023. The fair value of the embedded derivative liabilities will be assessed at subsequent reporting dates if material.

As of March 31, 2023, the development financing liability was classified as a long-term liability, as the Company expects the related repayments to take place between 2024 and 2030 for purposes of the model used to calculate its carrying value. The imputed interest rate on the unamortized portion of the development financing liability was approximately 19.2% as of March 31, 2023.

5. Collaboration and License Agreement

On January 6, 2023, the Company entered into a Collaboration and License Agreement (License Agreement) with Kaken Pharmaceuticals Co., Ltd (Kaken). The Company granted Kaken an exclusive license to develop and commercialize seladelpar (the Licensed Product) for the prevention or treatment of primary biliary cholangitis (PBC) in Japan.

Pursuant to the terms of the License Agreement, Kaken will bear the cost of, and be responsible for, among other things, conducting the clinical studies and other developmental activities for the Licensed Product in PBC in Japan as well as preparing and filing applications for regulatory approval and commercializing the Licensed Product in Japan. Kaken is obligated to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize, the Licensed Product in Japan, including obtaining pricing approval for the Licensed Product in Japan. The Company is obligated to supply to Kaken its requirements of Licensed Product for clinical and commercial use, which may be terminated upon specified circumstances, and with appropriate technology transfer.

The Company will deliver to Kaken data from its clinical trials, nonclinical studies and otherpre-clinical studies, as well as chemistry manufacturing and controls (CMC) data, minutes of meetings with regulatory authorities, and know-how within the Company's control that is reasonably necessary for Kaken to develop and seek regulatory approval of seladelpar for the treatment of PBC in Japan.

The Company is responsible for the completion of CMC development activities to enable future supply of the Licensed Product to Kaken and to enable Kaken to seek regulatory approval of the Licensed Product in Japan. The Company may also be requested by Kaken to conduct CMC activities specific to commercialization in Japan and provide other assistance.

In consideration of the license and other rights granted by the Company, Kaken made an upfront cash payment to the Company of ¥4.5 billion (approximately $34.2 million at contract inception date) and is obligated to pay potential milestone payments to the Company totaling up to¥17.0 billion (approximately $128.0 million at contract inception date) upon the achievement of certain regulatory and salesmilestones. The commercial supply of the Licensed Products to Kaken will be provided based on a commercial supply agreement to be negotiated between the parties in the future.

The License Agreement may be early terminated by either party for material breach, upon a party's insolvency or bankruptcy or upon a challenge by one party of any patents of the other party, and Kaken may terminate in specified situations, including for a safety concern, clinical failure or termination of an underlying in-license to the Company. Kaken may also terminate the License Agreement at its convenience with specified prior notice.

Pursuant to the License Agreement, the Company and Kaken agreed to establish a joint steering committee to provide strategic oversight of both parties' activities under the License Agreement.

The Company concluded that Kaken is a customer and that the arrangement represents a contract with a customer under the scope of ASC 606. The Company identified the following key promised goods and services under the arrangement: (1) the exclusive license to develop and commercialize seladelpar in Japan, including the initial transfer of the underlying technology and know-how; (2) delivery of data gathered through the execution of the Company's development activities for PBC to support Kaken's regulatory filings in Japan; and (3) completing the Company's global CMC development activities as necessary for the manufacture and supply of the Licensed Product to Kaken.

The license granted Kaken rights to certain intellectual property of the Company and was effective upon the execution of the License Agreement. However, the parties have not completed the transfer of the licensed technology and know-how by March 31, 2023 and as such the related performance obligation was not satisfied as of March 31, 2023. Further, the Company's data delivery performance obligation and the CMC development performance obligation have also not been delivered as of March 31, 2023.

As none of the performance obligations related to the License Agreement were satisfied as of March 31, 2023, no revenue was recognized during the quarter ended March 31, 2023. The initial transaction price consists of the upfront payment of ¥4.5 billion ($33.7 million at the time of receipt) which the Company received in January 2023. This amount was recorded in deferred revenue as of March 31, 2023 and is expected to be recognized during the year ending December 31, 2023 as various performance obligations are satisfied. The Company determined that the potential milestone payments and royalties, if recognized, are probable of significant revenue reversal, as their achievement is highly dependent on factors outside the Company's control, and therefore represent variable consideration that is fully constrained and excluded from the transaction price as of March 31, 2023.

6. Stockholders' Equity

Preferred and Common Stock Authorized

The Company is authorized to issue 10,000,000 shares of preferred stock and 200,000,000 shares of common stock as of March 31, 2023 and December 31, 2022.

Sale of Common Stock and Prefunded Warrants

On January 23, 2023, pursuant to a shelf registration statement on Form S-3, the Company issued a total of 11,821,428 shares of its common stock at $7.00 per share in an underwritten public offering. Concurrently, the Company sold to an existing investor who did not participate in the common stock sale a pre-funded warrant to purchase up to an aggregate of 2,142,857 shares of common stock at a purchase price of $6.9999 per share, which represents the per share public offering price for the common stock less the $0.0001 per share exercise price for the pre-funded warrant. The aggregate net proceeds to the Company from this offering was $92.4 million, after deducting underwriting discounts and commissions and other offering expenses.

The pre-funded warrants were determined to be equity classified; accordingly, proceeds received from their issuance were recorded as a component of stockholders' equity within additional paid-in capital. None of the January 2023 pre-funded warrants were exercised and therefore remain outstanding as of March 31, 2023.

Pursuant to the Company's public equity offering completed in November 2021, the Company issued pre-funded warrants to purchase 3,125,000 shares of common stock at a price of $3.9999 per share. These pre-funded warrants have an exercise price of $0.0001 per share, were fully exercisable upon issuance, and have no expiration date. The Company determined that the pre-funded warrants should be equity classified because they are freestanding financial instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, permit the holders to receive a fixed number of shares of common stock upon exercise, are indexed to the Company's common stock and meet the equity classification criteria. In February 2023, pre-funded warrants to purchase 625,000 shares of common stock from the November 2021 equity financing were net exercised, resulting in 624,992 shares of common stock issued to the holders of the pre-funded warrants. Pre-funded warrants to purchase 4,642,857 shares of common stock were outstanding as of March 31, 2023.

At-the-Market (ATM) Facility

In March 2023, the Company filed a registration statement on Form S-3 with the SEC and entered into an at-the-market facility (ATM) to sell up to $100.0 million of common stock under the registration statement. To date, the Company has not sold any shares of common stock under the ATM.

7. Net Loss Per Common Share

Basic net loss per share of common stock is based on the weighted-average number of shares of common stock equivalents outstanding during the period. Pre-funded warrants to purchase shares of common stock were included in the weighted-average common stock share equivalents outstanding for the three months ended March 31, 2023 and 2022.

In all periods presented, the Company's outstanding stock options were excluded from the calculation of net loss per share because their effect would be antidilutive. The following table sets forth the computation of basic and diluted net loss per share (in thousands, except share and per share amounts):

	Three Months Ended March 31,	
	2023	2022
Numerator:		
Net loss	$ (28,778)	$ (27,769)
Denominator:		
Weighted average number of:		
Common stock shares outstanding	93,701,240	84,677,939
Pre-funded warrants outstanding	4,269,841	3,125,000
Total	97,971,081	87,802,939
Net loss per share	$ (0.29)	$ (0.32)

The following table shows the total outstanding securities considered anti-dilutive and therefore excluded from the computation of net loss per share (in thousands):

	Three Months Ended March 31,	
	2023	2022
Common stock options	17,591	14,180
Incentive awards	85	101
Total	17,676	14,281

8. Stock Plans and Stock-Based Compensation

Stock Plans

As of March 31, 2023, there were3,067,331 shares available for future grants under the Company's 2013 Equity Incentive Plan andno shares available for grant under the Company's 2020 New Hire Plan. During the three months ended March 31, 2023, the Company granted 3,872,135 stock options which related to its option grants issued to employees and directors.

Stock-Based Compensation Expense

Stock-based compensation expense is included in the condensed consolidated statements of operations and comprehensive loss and is as follows (in thousands):

	Three Months Ended March 31,	
	2023	2022
Research and development	$ 1,601	$ 1,098
General and administrative	1,886	1,316
Total stock-based compensation expense	$ 3,487	$ 2,414

9. Commitments and Contingencies

Genfit Litigation

On January 15, 2021, Genfit S.A. (Genfit) filed a complaint against the Company in the U.S. District Court for the Northern District of California, alleging misappropriation of trade secrets and related causes of action based on the Company's receipt of a Genfit protocol synopsis for Genfit's Phase 3 clinical trial of its drug candidate elafibranor in patients with primary biliary cholangitis. An Amended Complaint was filed on April 16, 2021 with substantially the same allegations. Genfit sought damages in an unspecified amount as well as injunctive relief.On March 12, 2021, the Court granted a Temporary Restraining Order (later converted to a Preliminary Injunction), prohibiting the Company from accessing or disseminating the protocol synopsis, using any Genfit trade secrets contained therein or destroying any evidence related thereto. The Company filed a Motion to Dismiss the Amended Complaint that was granted on September 9, 2021, with leave to amend. Genfit filed a Second Amended Complaint on October 15, 2021 with substantially the same allegations and claims for relief as in the original complaint. The Company filed a Motion to Dismiss most of the Second Amended Complaint that was granted on January 21, 2022, without further leave to amend. What remained in the complaint was an alleged misappropriation of the protocol synopsis as a whole. The Company filed its Answer to what remained of the Second Amended Complaint on February 4, 2022.On February 21, 2023, the parties entered into a Settlement Agreement and the action was dismissed with prejudice. The Company did not admit to any liability and the litigation has been resolved completely.

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

Operating results for the three months ended March 31, 2023 are not necessarily indicative of results that may occur in future interim periods or for the full fiscal year.

This Quarterly Report on Form 10-Q contains statements indicating expectations about future performance and other forward-looking statements within the meaning of Section 27A of the Securities Act, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act, that involve risks and uncertainties. Words such as "may," "will," "should," "could," "would," "expect," "plan," "anticipate," "believe," "estimate," "project," "potential," "seek," "target," "goal," "intend," variations of such words, and similar expressions are intended to identify forward-looking statements. These statements appear throughout this Quarterly Report on Form 10-Q and are statements regarding our current expectation, belief, or intent, primarily with respect to our operations and related industry developments. Examples of these statements include, but are not limited to, statements regarding our expectations with respect to the following: our business and scientific strategies; the progress of our product development programs and the timing of results; regulatory submissions and approvals; the impact of COVID-19 on our company and operations; our drug discovery technologies; our research and development expenses; protection of our intellectual property; sufficiency of our cash and capital resources and the need for additional capital; and our operations and legal risks. You should not place undue reliance on these forward-looking statements. Our actual results and the timing of events may differ significantly from the results discussed in the forward-looking statements for many reasons. Factors that might cause such a difference include those discussed under the caption "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. These and many other factors could affect our future financial and operating results. We undertake no obligation to update any forward-looking statement to reflect events after the date of this Quarterly Report. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this Quarterly Report on Form 10-Q. While we believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into or review of all relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely on these statements.

Overview

CymaBay Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on developing innovative therapies for patients with liver and other chronic diseases with high unmet medical need.

Our lead product candidate, seladelpar, is a potent and selective agonist of peroxisome proliferator activated receptor delta (PPARd), a nuclear receptor that regulates genes directly or indirectly involved in the synthesis of bile acids/sterols, metabolism of lipids and glucose, inflammation, and fibrosis. We have been focused on developing seladelpar for the treatment of primary biliary cholangitis (PBC), an autoimmune disease that causes progressive destruction of the bile ducts in the liver resulting in impaired bile flow (cholestasis) and inflammation.

Seladelpar—Primary Biliary Cholangitis (PBC)

In July 2022, we completed enrollment of 193 patients in RESPONSE, a52-week, double-blind, placebo-controlled, randomized, global Phase 3 registration study evaluating the safety and efficacy of seladelpar in PBC. The study enrolled patients who have an inadequate response to, or intolerance to ursodeoxycholic acid (UDCA), in a 2:1 randomization to oral, once daily seladelpar 10 mg or placebo. The primary outcome measure will be the composite biochemical responder rate at 52 weeks. A responder is defined as a patient who achieves an alkaline phosphatase (ALP) level less than 1.67 times the upper limit of normal with at least a 15% decrease from baseline and has a normal level of total bilirubin. Additional key outcomes of efficacy will compare the rate of normalization of ALP at 52 weeks and the change from baseline in level of pruritus at six months for patients with moderate to severe pruritus at baseline assessed by a numerical rating scale (NRS) recorded with an electronic diary. We expect to release top line data for RESPONSE in the third quarter of 2023.

In addition to RESPONSE, we are also actively enrolling eligible patients for our ASSURE trial, an open-label, long-term study intended to collect additional long-term safety and efficacy data to support registration. ASSURE is open to patients who were eligible for our previous long-term extension study that was terminated early in late 2019, including those patients from our previously completed Phase 2 open label study and our Phase 3 ENHANCE study, as well as patients who complete treatment in RESPONSE and certain Phase 1 studies. The ASSURE trial currently has over 200 patients enrolled and is expected to ultimately enroll in excess of 300 patients.

MBX-2982

MBX-2982 targets G protein-coupled receptor 119 (GPR119), a receptor that interacts with bioactive lipids known to stimulate glucose-dependent insulin secretion. In November 2020, we announced a Phase 2a proof-of-pharmacology study to assess whether MBX-2982 can enhance glucagon secretion during insulin-induced hypoglycemia in subjects with T1D. The study is actively enrolling patients. If successful, studies to evaluate MBX-2982 as a potential preventive therapy for hypoglycemia in patients with T1D may be warranted. The study is being led by the AdventHealth Translational Research Institute in Orlando, Florida and is fully funded by The Leona M. and Harry B. Helmsley Charitable Trust. CymaBay retains full commercial rights to MBX-2982. We believe MBX-2982 may also have utility in various inflammatory diseases and we are currently exploring potential opportunities to advance development.

COVID-19

As a result of the COVID-19 situation, we may experience future disruptions that could impact aspects of our business, including our progress towards the initiation and completion of certain clinical trials and other drug development activities. COVID-19 has disrupted, and may continue to disrupt, aspects of our business, in particular in regard to the initiation and operation of clinical trial sites. Our collective research and development personnel and vendors, including our clinical research organization partners and contract manufacturing organizations, have adapted to COVID-19 as they continue to progress toward completion of our clinical trials. Other areas of potential risk include (i) operational interruptions or delays in our drug regulator interactions, whether with the FDA or comparable foreign regulatory agencies, (ii) the availability of third-party information systems and other cloud-based services that affect our ability to maintain our established financial reporting functions and internal controls over financial reporting, and (iii) our continued use of partially-remote (hybrid) operations, which could increase our cyber-security risk, create data accessibility concerns and may make us more susceptible to communication disruptions that in turn can adversely impact our business operations.

To date, there has been no adverse impact by COVID-19 on our ability to maintain our established financial reporting functions and internal controls over financial reporting; however, we cannot at this time predict the specific extent, duration, or full impact that the continuing COVID-19 situation will have on our future consolidated financial condition and operations. The impact of COVID-19 on our consolidated financial performance will depend on future COVID-19 developments, if any, which could result in unexpected costs to us. These developments and the impact of COVID-19 on the financial markets and the overall economy are highly uncertain. If the financial markets and/or the overall economy are impacted for an extended period, our results may be adversely affected.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of these condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at the date of the condensed consolidated financial statements, as well as the reported revenues and expenses during the reporting periods. We base our estimates on historical experience and on various other factors that we believe to be materially reasonable under the circumstances, the results of which form our basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources, and evaluate our estimates on an ongoing basis. Actual results may materially differ from those estimates under different assumptions or conditions.

There have been no changes to our critical accounting policies, except for our revenue recognition policy with respect to the Kaken license agreement, since we filed our Annual Report on Form 10-K for the year ended December 31, 2022 with the SEC on March 23, 2023. For a description of our critical accounting policies and estimates, please refer to our Annual Report on Form 10-K.

Recent Accounting Pronouncements

Refer to *Note 2—Summary of Significant Accounting Policies* in the notes to our unaudited interim condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q, for a discussion of recent accounting pronouncements.

Results of Operations

General

To date, we have not generated any income from operations. As of March 31, 2023, we have an accumulated deficit of $901.6 million, primarily as a result of expenditures for research and development, general and administrative expenses and net interest expenses from inception to that date. Currently, our lead product candidate is in late stage development but will require additional work and regulatory approval before it can be fully licensed or commercialized. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future and there can be no assurance that we will ever generate sufficient revenue to achieve and sustain profitability. Until we can generate sufficient product revenue, which we may never do, we will need to finance future cash needs through potential collaborative, partnering or other strategic arrangements, as well as through equity offerings, debt financings or a combination of the foregoing.

Operating Results

Our results of operations for the three months ended March 31, 2023 and 2022 are presented below (in thousands):

	Three Months Ended March 31,		Change Q1
	2023	2022	2023 vs. 2022
Operating expenses:			
Research and development	$ 18,551	$ 18,415	$ 136
General and administrative	8,324	6,087	2,237
Total operating expenses	26,875	24,502	2,373
Loss from operations	(26,875)	(24,502)	(2,373)
Other income (expense), net:			
Interest income	2,013	98	1,915
Interest expense	(4,403)	(3,365)	(1,038)
Other income	487	—	487
Total other income (expense), net	(1,903)	(3,267)	1,364
Net loss	$(28,778)	$(27,769)	$ (1,009)

Research & Development Expenses

Conducting research and development is central to our business model. Research and development expenses increased $0.1 million to $18.6 million from $18.4 million for the three months ended March 31, 2023 and 2022, respectively. We expect that our research and development expenses will increase in the future primarily due to costs associated with our ongoing late-stage development of seladelpar in PBC.

Research and development expenses are detailed further in the table below (in thousands):

	Three Months Ended March 31,		Change Q1
	2023	2022	2023 vs 2022
Project costs:			
Seladelpar PBC clinical studies	$ 7,318	$ 9,273	$ (1,955)
Seladelpar drug manufacturing & development	1,329	2,256	(927)
Seladelpar and non-seladelpar other studies	689	100	589
Total project costs	9,336	11,629	(2,293)
Internal research and development costs	9,215	6,786	2,429
Total research and development	$18,551	$18,415	$ 136

Our project costs consist primarily of:

- expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and a substantial portion of our preclinical activities;
- the cost of acquiring materials and manufacturing drug products for use in clinical trial and other research activities; and
- other costs associated with development activities, including additional studies.

Internal research and development costs consist primarily of salaries and related fringe benefits costs for our employees (such as workers' compensation and health insurance premiums), stock-based compensation charges, travel costs, and overhead expenses. Internal costs generally benefit multiple projects and are not separately tracked per project.

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

Total project costs decreased $2.3 million to $9.3 million from $11.6 million for the three months ended March 31, 2023 and 2022, respectively. The decrease was mostly due to the completion of enrollment of our RESPONSE trial and lower spending in drug manufacturing and development for PBC during the three months ended March 31, 2023. Project costs for the three months ended March 31, 2023 and 2022 primarily consisted of seladelpar-related clinical trial expenses for PBC. Internal research and development costs increased by $2.4 million to $9.2 million from $6.8 million for the three months ended March 31, 2023 and 2022, respectively, primarily due to higher employee compensation incurred in the three months ended March 31, 2023 as compared to the three months ended March 31, 2022, as we continued to hire additional research and development personnel to support our clinical studies. As we continue to progress late-stage development of seladelpar in PBC we expect research and development expenses to increase in the future.

General and Administrative Expenses

General and administrative expenses consist principally of personnel-related costs, professional fees for legal, consulting, and accounting services, rent, and other general operating expenses not otherwise included in research and development.

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

General and administrative expenses increased by $2.2 million to $8.3 million from $6.1 million for the three months ended March 31, 2023 and 2022, respectively. The increase was driven primarily by an increase in in headcount in general and administrative personnel in the three months ended March 31, 2023 when compared to three months ended March 31, 2022, as we continue to add administrative personnel and expand our infrastructure in support of our drug development activities. We expect these types of general and administrative expenses to continue to increase in the future as we further expand support for our ongoing drug development activities and as we begin to conduct initiatives to plan and prepare for potential commercialization of seladelpar in PBC.

Other Income (Expense), Net

Other income (expense), net includes interest expense related to the accretion of the development financing liability recorded in connection with the July 2021 Abingworth Development Financing Agreement (the Financing Agreement) using the effective interest method, net of interest income earned on our marketable securities portfolio and other income. Other income (expense), net, decreased $1.4 million to $1.9 million from $3.3 million for the three months ended March 31, 2023 and 2022, respectively primarily due to an increase in interest income of $1.9 million that was driven by higher prevailing interest rates from investments held in our portfolio and an increase in other income of $0.5 million comparatively. This increase in interest income was partially offset by an increase in interest expense of $1.0 million related to our Abingworth development financing liability.

Liquidity and Capital Resources

We have financed our operations primarily through the sale of equity securities, licensing fees, issuance of debt and collaborations with third parties. At March 31, 2023, cash, cash equivalents and marketable securities totaled $236.4 million, compared to $135.5 million at December 31, 2022.

Development Financing

On July 30, 2021, we entered into a Development Financing Agreement (the Financing Agreement) with Abingworth to obtain funding to support our development of seladelpar for the treatment of PBC. We received $75.0 million in funding pursuant to the Financing Agreement, of which $25 million was received in August 2021, $25 million was received in November 2021 and $25 million was received in January 2022.

Collaboration and License Agreement

On January 6, 2023, we entered into a Collaboration and License Agreement (the License Agreement) with Kaken Pharmaceutical Co., Ltd. Pursuant to the License Agreement, we granted Kaken an exclusive license to develop and commercialize seladelpar for the treatment of PBC in Japan. In exchange for the license and other rights granted by us, Kaken paid us ¥4.5 billion ($34.2 million at exchange rates in effect at contract inception date) in January 2023 and they are also obligated to make aggregate potential future milestone payments to us totaling up to ¥17.0 billion ($128.0 million at exchange rates in effect at contract inception date) upon Kaken's achievement of certain regulatory and sales milestones. We are obligated to manufacture and supply seladelpar to Kaken for use in the territory in exchange for payments from Kaken as defined in the License Agreement. We will deliver to Kaken data from our clinical trials, nonclinical studies and other pre-clinical data, chemistry manufacturing and controls (CMC) data, minutes of meetings with regulatory authorities, and know-how that is controlled by us that is reasonably necessary for Kaken to seek regulatory approval in Japan. We may also be requested by Kaken to conduct CMC activities specific to commercialization in Japan and provide other assistance.

The License Agreement is effective until the date upon which (a) the royalty term has expired in Japan for the final licensed product, or (b) the License Agreement is earlier terminated (the Initial Term). After the Initial Term, the License Agreement will be automatically renewed for 2-year periods, unless either party has given the other party a written notice not to renew the License Agreement.

The License Agreement may be early terminated by either party for material breach, upon a party's insolvency or bankruptcy or upon a challenge by one party of any patents of the other party, and Kaken may terminate in specified situations, including for a safety concern, clinical failure or termination of an underlying in-license to us from Janssen Pharmaceutica NV. Kaken may also terminate the License Agreement at its convenience with specified prior notice.

Pursuant to the License Agreement, we and Kaken agreed to establish a joint steering committee to provide strategic oversight of both parties' activities under the License Agreement.

During the quarter ended March 31, 2023, the parties did not complete the transfer of the licensed technology and know-how subject to the License Agreement and as such no revenue was recognized on the associated performance obligation. Further, our data delivery performance obligation and the CMC development performance obligation have also not been delivered as of March 31, 2023, and accordingly, no revenue was recognized during the quarter ended March 31, 2023 for each of these performance obligations. We determined that the potential milestone payments and royalties, if recognized, are probable of significant revenue reversal as their achievement is highly dependent on factors outside our control, and therefore represent variable consideration that is fully constrained and excluded from the transaction price as of March 31, 2023.

Sale of Common Stock and Pre-funded Warrant

On January 23, 2023, we sold 11,821,428 shares of common stock at $7.00 per share and a pre-funded warrant to purchase 2,142,857 shares of common stock at $6.9999 per share in a public equity offering (the January 2023 public equity offering), for total gross offering proceeds of approximately $97.7 million. The net proceeds from this offering were $92.4 million after deducting the underwriting discount and other offering expenses. We anticipate using the offering proceeds to fund ongoing development of seladelpar and for working capital and general corporate purposes.

At-the-Market (ATM) Facility

In March 2023, we filed a registration statement on Form S-3 with the SEC and entered into an at-the-market facility (ATM) to sell up to $100.0 million of common stock under the registration statement. To date, we have not sold any shares of common stock under the ATM.

Cash Flows

The following table sets forth a summary of the net cash flow activity for each of the periods indicated below (in thousands):

	Three Months Ended March 31,	
	2023	2022
Net cash provided by (used in) operating activities	$ 6,431	$(25,362)
Net cash (used in) investing activities	(60,642)	(50,990)
Net cash provided by financing activities	93,070	24,541
Net increase (decrease) in cash and cash equivalents	$ 38,859	$(51,811)

Operating Activities: Net cash provided by operating activities for the three months ended March 31, 2023 increased by $31.8 million to $6.4 million as compared to net cash used in operating activities of $25.4 million for the same period in the prior year, primarily due to an increase of $33.7 million of deferred collaboration revenue related to cash received from a collaboration arrangement with Kaken, partially offset by an increase in our net loss to $28.8 million from $27.8 million in the comparable prior year period due to the expansion of late-stage clinical trial activities related to the seladelpar development program. In addition, cash was used to fund changes in our working capital due to the timing of payments.

Investing Activities: Net cash used in investing activities was $60.6 million for the three months ended March 31, 2023, compared to $51.0 million provided by investing activities for the same period in the prior year, primarily due to the timing of our investments and maturities of marketable securities and portfolio risk management.

Financing Activities: Net cash provided by financing activities was $93.0 million for the three months ended March 31, 2023, which mostly consisted of net proceeds of $92.4 million received from the January 2023 public equity offering.

Capital Requirements

We have incurred operating losses since inception and had an accumulated deficit of $901.6 million at March 31, 2023. As of March 31, 2023, we had cash, cash equivalents and marketable securities of approximately $236.4 million, which we believe is sufficient to fund our current operating plan through the third quarter of 2024.

We expect to continue to incur substantial expenses related to our development activities for the foreseeable future as we continue product development for seladelpar. Since product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later stage clinical trials, we expect that our research and development expenses will increase in the future. We will therefore continue to require additional financing to develop our products and fund future operating losses and will seek funds through equity financings, debt, collaborative or other arrangements with corporate sources, or through other sources of financing. It is unclear if or when any such financing transactions will occur, on satisfactory terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. If adequate funds are not available to us, it could have a material adverse effect on our business, results of operations, and financial condition.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable to Smaller Reporting Companies.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation as of March 31, 2023 under the supervision and with the participation of our management, including our President and Chief Executive Officer and Vice President, Finance, of the effectiveness of our "disclosure controls and procedures," which are defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), as controls and other procedures of a company that are designed to ensure that the information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our President and Chief Executive Officer and Vice President, Finance, as appropriate, to allow timely decisions regarding required disclosure. Based upon that evaluation, our President and Chief Executive Officer and Vice President, Finance concluded that our disclosure controls and procedures were effective as of March 31, 2023.

Limitations on the Effectiveness of Controls

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the controls are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our President and Chief Executive Officer and Vice President, Finance have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were sufficiently effective to provide reasonable assurance that the objectives of our disclosure control system were met.

Changes in Internal Controls

There were no changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2023, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We have not experienced any material impact to our internal controls over financial reporting despite the fact that most of our employees are working in a hybrid remote model due to the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 situation on our internal controls to minimize the impact on their design and operating effectiveness.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

On January 15, 2021, Genfit S.A. (Genfit) filed a complaint against us in the U.S. District Court for the Northern District of California, alleging misappropriation of trade secrets and related causes of action based on our receipt of a Genfit protocol synopsis for Genfit's Phase 3 clinical trial of its drug candidate elafibranor in patients with primary biliary cholangitis. An Amended Complaint was filed on April 16, 2021 with substantially the same allegations. Genfit sought damages in an unspecified amount as well as injunctive relief. On March 12, 2021, the court granted a Temporary Restraining Order (later converted to a Preliminary Injunction), prohibiting us from accessing or disseminating the protocol synopsis, using any Genfit trade secrets contained therein or destroying any evidence related thereto. We filed a Motion to Dismiss the Amended Complaint that was granted on September 9, 2021, with leave to amend. Genfit filed a Second Amended Complaint on October 15, 2021 with substantially the same allegations and claims for relief as in the original complaint. We filed a Motion to Dismiss the Second Amended Complaint that was granted on January 21, 2022, without further leave to amend. What remained in the complaint was an alleged misappropriation of the protocol synopsis as a whole. We filed our Answer to what remained of the Second Amended Complaint on February 4, 2022. On February 21, 2023, the parties entered into a Settlement Agreement and the action was dismissed with prejudice. We did not admit to any liability and the litigation has been resolved completely.

Item 1A.

Risk Factors

In addition to the factors discussed elsewhere in this report, the following are important factors that could cause actual results or events to differ materially from those contained in any forward-looking statements made by us or on our behalf. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not currently known to us or that we deem immaterial also may impair our business operations. If any of the following risks or such other risks actually occur, our business could be harmed.

RISK FACTOR SUMMARY

We are subject to a number of risks that if realized could materially harm our business, prospects, operating results, and financial condition. Some of the more significant risks and uncertainties we face include those summarized below. The summary below is not exhaustive and is qualified by reference to the full set of risk factors set forth in Item 1A of this Form 10-Q "Risk Factors." Please carefully consider all the information in this Form10-Q, including the full set of risks set forth in the "Risk Factors" section, and in our other filings with the SEC before making an investment decision regarding CymaBay.

Risks Related to Our Financial Condition and Capital Requirements

- We have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. We may need to raise additional equity and/or debt capital to fund our continued operations, including clinical trials and other product development. In the event we do not successfully raise sufficient funds to finance our product development activities, we will curtail our product development and other activities commensurate with the magnitude of the shortfall or our product development activities may cease altogether.
- Failure to remain in compliance with our obligations under the Development Financing Agreement with Abingworth could lead to acceleration of potentially significant payments to Abingworth.
- Our ability to generate future revenues from product sales is uncertain and depends upon our ability to successfully develop, obtain regulatory approval for, and commercialize product candidates, including most importantly, seladelpar.
- Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Risks Related to Clinical Development and Regulatory Approval

- Drug development and obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain.
- Serious complications or side effects in connection with the use or development of our product candidates could lead to delay or discontinuation of development of our product candidates.

Risks Related to COVID-19

- Our business may be adversely affected by the effects ofthe COVID-19 situation, including those impacting our ability to enroll and conduct critical clinical trials, as well as impacts to our other development efforts, administrative personnel and third-party service providers.

Risks Related to Our Reliance on Third Parties

- Our manufacturing partners and other service providers, including CROs managing our clinical trials, may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates and future products.

Risks Related to Commercialization of Our Product Candidates

- We have never successfully commercialized a product. If any of our product candidates receive marketing approval, they may nonetheless be unable to gain sufficient market acceptance by physicians, patients, health care payors and others in the medical community.
- If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our products, we may be unable to generate any revenue.
- The commercial success of our products is subject to significant competition from products that may be superior to, or more cost effective than, our products.

Risks Related to Our Intellectual Property

- We may not be able to protect the confidentiality of our trade secrets, and our patents or other means of defending our intellectual property may be insufficient to protect our proprietary rights.
- Patents or proprietary rights of others may restrict our development, manufacturing, and/or commercialization efforts and subject us to litigation and other proceedings that could find us liable for damages.

Other Risks Factors – Risks Related to Employees, Information Technology, and Owning Our Common Stock

- Our business is dependent on our key personnel and will be harmed if we cannot recruit and retain leaders in our development, administrative, and commercial organizations.
- Significant disruptions of information technology systems or breaches of data security could adversely affect our business.
- Changes in and failures to comply with United States and foreign privacy and data protection laws, regulations and standards may adversely affect our business, operations and consolidated financial performance.
- Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

Risks Related to Our Financial Condition and Capital Requirements

We will need additional capital in the future to sufficiently fund our operations and research.

We have incurred significant net losses since our inception. We anticipate that we will continue to incur significant losses for the foreseeable future, and we may never achieve or maintain profitability. As of March 31, 2023, we had cash, cash equivalents and marketable securities totaling $236.4 million. To date, we have raised capital primarily through equity financings, licensing transactions and a structured finance arrangement. For example, in January 2023, we entered into a Collaboration and License Agreement with Kaken Pharmaceutical Co., Ltd. (Kaken), granting Kaken an exclusive license to commercialize and market seladelpar for the prevention or treatment of primary biliary cholangitis (PBC) in Japan in consideration for an upfront payment to the Company of $34.2 million that was paid in January 2023, potential milestone payments to the Company totaling up to ¥17.0 billion (approximately $128.0 million at contract inception date) for the achievement of certain regulatory and sales milestones in Japan and additional payments to the Company for the supply of seladelpar to Kaken. In January 2023, we sold 11,821,428 shares of common

stock at $7.00 per share and a pre-funded warrant to purchase 2,142,857 shares of common stock at $6.9999 per share in a public equity offering for total gross offering proceeds of $97.7 million. In July 2021, we entered into a Development Financing Agreement with an affiliate of Abingworth LLP pursuant to which Abingworth provided $75 million in funding to the Company. We may need to raise additional equity and/or debt capital or enter into strategic transactions to fund our continued operations, including clinical trials, other product development and pre-commercialization activities. Our monthly spending levels vary based on new and ongoing development and corporate activities. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete.

In the event we do not successfully raise sufficient funds to finance our product development activities, we will curtail our product development activities and other activities commensurate with the magnitude of the shortfall and our product development activities may cease altogether. To the extent that the costs of ongoing development exceed our current estimates and we are unable to raise sufficient additional capital to cover such additional costs, we will need to reduce operating expenses, sell assets, enter into strategic transactions, or effect a combination of the above. No assurance can be given that we will be able to enter into any of such transactions on acceptable terms, if at all.

Our future funding requirements and sources will depend on many factors, including but not limited to the following:

- the rate of progress and cost of our clinical studies;
- the need for additional or expanded clinical studies;
- the rate of progress and cost of our Chemistry, Manufacturing and Control development, registration, validation and commercial programs;
- the timing, economic and other terms of any licensing, collaboration or other similar arrangement into which we may enter;
- the costs and timing of seeking and obtaining FDA and other regulatory approvals;
- the extent of our other development activities;
- the costs of our pre-commercialization activities;
- the costs of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- macroeconomic conditions that may impact the Company's operations and financial condition; and
- the effect of competing products and market developments.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing development and commercialization efforts, which would have a material adverse effect on our business, operating results, prospects, and on our ability to develop our product candidates.

Failure to remain in compliance with our obligations under the Development Financing Agreement (the Financing Agreement) with Abingworth could lead to the acceleration of potentially significant payments to Abingworth.

In July 2021, we entered into a Development Financing Agreement with Abingworth, pursuant to which Abingworth has provided $75 million in funding to us to support our development of seladelpar for the treatment of PBC. Pursuant to the Financing Agreement, we are required to use commercially reasonable efforts to develop seladelpar and complete our development program in accordance with the Financing Agreement and an agreed timeline. In return, we are obligated to pay to Abingworth (1) upon the first to occur of regulatory approval of seladelpar for the treatment of PBC in the U.S., U.K., Germany, Spain, Italy or France (Regulatory Approval), fixed success payments equal to 2.0x of the funding provided and (2) variable success payments equal to 1.1x of the funding provided upon first reaching certain U.S. product sales milestones. At the time that Abingworth receives, collectively, an aggregate of 3.1x of the funding provided, our payment obligations under the Financing Agreement will be fully satisfied.

The Financing Agreement terminates upon the payment of all payments owing to Abingworth, unless earlier terminated. The Agreement may be earlier terminated in a number of circumstances including (i) by Abingworth if we fail to use commercially reasonable efforts to develop seladelpar as set forth in the Financing Agreement or if we fail to make required payments (Fundamental Breach) or (ii) by either party if the other party materially breaches the Agreement (Material Breach). In certain instances, upon the termination of the Financing Agreement, we will be obligated to pay Abingworth a multiple of the amounts paid to us under the Agreement, including specifically,

(i) 310% of such amounts in the event that Abingworth terminates the agreement due to (x) a Fundamental Breach, (y) our bankruptcy, or (z) a safety concern resulting from gross negligence on our part or due to a safety concern that was material on the Effective Date and the material data showing such safety concern was not publicly known, disclosed to Abingworth, or in the diligence room made available to Abingworth,

(ii) 200% of such amounts in the event the Agreement is terminated due to (x) our Material Breach or (y) the security interests of Abingworth being invalidated or terminated other than as set forth in the Financing Agreement, and

(iii) 100% of such amounts in the event of certain irresolvable disagreements within the executive review committee overseeing our development of seladelpar.

In addition, if, following certain terminations, we continue to develop seladelpar for the treatment of PBC and obtain Regulatory Approval, we will make the payments to Abingworth as if the Financing Agreement had not been terminated, less any payments made upon termination.

The payments required under the Financing Agreement are significant. Failure to raise sufficient capital or generate sufficient revenue to make such payments if and as they become due, or failure to otherwise finance such payments would have a material adverse effect on our business. In addition, if we are unable to comply with our obligations under the Financing Agreement and/or one of the termination events described above occurs our payments obligations thereunder may be accelerated. The acceleration of payments under the Financing Agreement would have a material impact on our business and we may not be able to make such payments at such time.

Our ability to generate future revenues from product sales is uncertain and depends upon our ability to successfully develop, obtain regulatory approval for, and commercialize product candidates.

Our ability to generate revenue and achieve profitability depends on our ability, alone or with collaborators, to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize, product candidates. We do not anticipate generating revenues from sales of our product candidates in the near future, if ever.

Conducting preclinical testing and clinical trials is a time-consuming, expensive, and uncertain process that takes years to complete, and we may never generate the necessary data required to obtain regulatory approval and achieve product sales. Our anticipated development costs would likely increase if we do not obtain favorable results or if development of our product candidates is delayed. In particular, we would likely incur higher costs than we currently anticipate if development of our product candidates is delayed because we are required by a regulatory authority such as the FDA to perform studies or trials in addition to those that we currently anticipate. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to predict the timing or amount of any increase in our anticipated development costs.

In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs in connection with commercialization. As a result, we cannot assure you that we will be able to generate revenues from sales of any approved products, or that we will achieve or maintain profitability even if we do generate sales.

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

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, licensing arrangements and other marketing and distribution arrangements. We do not have any committed external source of funds. If appropriate opportunities become available, we may seek to raise additional equity and/or debt capital to fund our continued operations, including clinical trials and other product development.

To raise additional funds to support our operations, we may sell additional equity or debt securities, enter into collaborations, strategic alliances, or licensing arrangements or other marketing or distribution arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interests of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, and declaring dividends, and may impose limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

If we raise additional funds through collaborations, strategic alliances, licensing arrangements or other marketing or distribution arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us.

If we are unable to expand our operations or otherwise capitalize on our business opportunities, our business, financial condition and results of operations could be materially adversely affected. 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 commercialization efforts, or grant others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults ornon-performance by financial institutions could adversely affect our current financial condition and projected business operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank (SVB), where we hold a small portion of our cash and cash equivalents, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (FDIC), as receiver. On March 12, 2023, the Department of the Treasury, the Federal Reserve and the FDIC jointly released a statement that depositors at SVB would have access to their funds, even those funds in excess of FDIC insurance limits, under a systemic risk exception. As of March 13, 2023, we had access to our cash and cash equivalents at SVB; however, there is uncertainty in the markets regarding the stability of regional banks and the safety of deposits in excess of the FDIC insured deposit limits. The ultimate outcome of these events cannot be predicted, but these events could have a material adverse effect on our business operations if our ability to access funds at SVB or any other banks we use is compromised.

Risks Related to Clinical Development and Regulatory Approval

We depend on the success of our product candidates and we may not obtain regulatory approval or successfully commercialize our product candidates.

We have not marketed, distributed or sold any products. The success of our business depends upon our ability to develop and commercialize our product candidates. The success of any product candidate will depend on many factors, including the following:

- successful enrollment and completion of clinical trials, including, in the case of RESPONSE, sufficient subjects that receive liver biopsies;
- the successful and timely collection and analysis of trial data;
- receipt of marketing approvals from the FDA and regulatory authorities outside the United States for the product candidate;
- establishing commercial manufacturing capabilities by making arrangements with third-party manufacturers;
- launching commercial sales of the product, whether alone or in collaboration with others;
- acceptance of the product by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- a continued acceptable safety profile of the product following marketing approval; and
- obtaining, maintaining, enforcing and defending intellectual property rights and claims.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidate, which would materially harm our business.

We depend on the successful completion of clinical trials for our product candidates.

Before obtaining regulatory approval for the sale of our product candidates, we must complete our current clinical trials as well as potentially additional clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

We may experience a number of unforeseen events during clinical trials for our product candidates, including seladelpar, that could delay or prevent the commencement and/or completion of our clinical trials, including the following:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the clinical study protocol may require one or more amendments delaying study completion;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, we may have to compete with other clinical trials to enroll eligible subjects, or subjects may drop out of these clinical trials at a higher rate than we anticipate;
- the number of patients in our RESPONSE clinical trial that receive biopsies may be insufficient to satisfy regulatory requirements;
- clinical investigators or study subjects may fail to comply with clinical study protocols;
- trial conduct and data analysis issues may occur, including, but not limited to, failure to collect and analyze data in a timely manner, data entry and/or labeling errors or data analysis errors;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;
- geo-political turmoil between Russia and Ukraine and/or continuing military actions in Ukraine may interfere with our wind down of clinical trials of seladelpar in Russia and analysis of relevant data;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our clinical trial materials or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators to suspend or terminate the trials.

Because successful development of product candidates is uncertain, we are unable to estimate the actual funds required to complete research and development and commercialize our products under development.

Negative or inconclusive results of our future clinical trials of product candidates could cause the FDA or other regulatory authorities to require that we repeat or conduct additional clinical studies. If later stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for our product candidates may be adversely impacted. For example, we expect to release top line data for RESPONSE in the third quarter of 2023, and if positive, to submit an NDA seeking approval from the FDA for seladelpar for the second line treatment of PBC. The combined data from our trials may be inconclusive or may not be sufficient to gain approval from the FDA.

Geo-political turmoil between Russia and Ukraine and continuing military actions in Ukraine have caused us to suspend clinical trial activity in Ukraine and wind down clinical trial activity in Russia.

We have a small number of clinical sites in Russia in our RESPONSE clinical trial and in our ASSURE clinical trial. Because of continuing military action in Ukraine we suspended all clinical trial activity in Ukraine. Ongoing geo-political turmoil and continuing military action in the region, together with widening sanctions imposed on Russia, have also caused us to begin to wind down clinical trial activity in Russia. We expect clinical trial activity in Russia to terminate by the end of the fourth quarter of 2023. The ongoing military action and sanctions may still affect our RESPONSE and ASSURE clinical trials in Russia prior to completion of our wind down. In addition, sites and site personnel may not be able to continue in the trials and we may need to suspend or terminate the trials in Russia prior to the end of our expected wind down. While we have only a small number of clinical sites and enrolled patients in Russia, these disruptions and potential suspensions could complicate the analysis of data from subjects in Russia.

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.

Clinical testing is expensive, difficult to design and implement, can take many years to complete, and is uncertain as to outcome. We may experience delays in clinical trials at any stage of development and testing of our product candidates and any delay could result in increased costs to us. Any clinical trials we undertake may not begin on time, have an effective design, enroll a sufficient number of subjects, or be completed on schedule, if at all. The impact of the ongoing COVID-19 situation is also uncertain, and may create additional delays in completing our clinical trials.

Events that may result in delays or unsuccessful completion of clinical trials include the following:

- reluctance of patients to enroll in our clinical trials due to COVID-19;
- personnel shortages at clinical sites due to the COVID-19 situation that impacts our timeline or operations at clinical trial sites participating in our clinical trials;
- competition for eligible patients from competing clinical trials;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA or other regulatory authorities on final trial design;
- imposition of a clinical hold following a reported safety event;
- an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical trial sites;
- delays in obtaining required institutional review board (IRB) approval at each site;
- delays in recruiting suitable patients to participate in a trial;
- delays in having subjects complete participation in a trial or return for post-treatment follow-up;
- delays caused by subjects dropping out of a trial due to side effects or otherwise;
- changes to treatment guidelines or the introduction of a new standard of care;
- delays caused by clinical sites dropping out of a trial;
- time required to add new clinical sites;
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials; and
- delays in importing clinical trial materials into foreign countries where our clinical trials are being conducted.

If initiation or completion of any clinical trials we may undertake for our product candidates is delayed for any of the above reasons, our development costs may increase, the approval process could be delayed, any periods during which we may have the exclusive right to commercialize our product candidates may be reduced and our competitors may bring products to market before us. Any of these events could impair our ability to generate revenues from product sales, which would have a material adverse effect on our business.

Our product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

In May 2016, we announced results of a High Dose Phase 2 clinical study of seladelpar in patients with PBC. During the course of this trial three cases of asymptomatic, reversible transaminase elevations occurred, and we made the decision to discontinue the study early after review of safety and efficacy data demonstrated a need for further dose reduction to optimize clinical safety and efficacy. The emergence of adverse events (AEs) and histological observations in subsequent seladelpar clinical trials could prevent us from further developing seladelpar or could result in the denial of regulatory approval.

Furthermore, if any of our approved products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including the following:

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution in a form of a risk evaluation and mitigation strategy (REMS) plan;
- regulatory authorities may require the addition of labeling statements, such as black box or other warnings or contraindications that could diminish the usage of the product or otherwise limit the commercial success of the affected product;
- we may be required to change the way the product is administered or to conduct additional clinical studies;
- we may choose to discontinue sale of the product;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our product candidates.

Potential conflicts of interest arising from relationships with principal investigators for our clinical studies and any related compensation with respect to clinical studies could adversely affect the drug approval process.

Principal investigators for our clinical studies may serve as scientific advisors or consultants to us or may be affiliated with our other service providers, including clinical research organizations or site management organizations, and from time to time receive cash compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical study site or in the applicable study may be questioned or jeopardized.

We may be subject to costly claims related to our clinical studies and may not be able to obtain adequate insurance.

Because we conduct clinical studies in humans, we face the risk that the use of seladelpar or other product candidates will result in adverse side effects. We cannot predict the possible harms or side effects that may result from our clinical studies. Although we have clinical study liability insurance, our insurance may be insufficient to cover any such events. There is also a risk that we may not be able to continue to obtain clinical study coverage on acceptable terms. In addition, we may not have sufficient resources to pay for any liabilities resulting from a claim excluded from, or beyond the limit of, our insurance coverage. There is also a risk that third parties that we have agreed to indemnify could incur liability. Any litigation arising from our clinical studies, even if we are ultimately successful, would consume substantial amounts of our financial and managerial resources and may create adverse publicity.

After the completion of our clinical trials, we cannot predict whether or when we will obtain regulatory approval to commercialize our product candidates and we cannot, therefore, predict the timing of any future revenue from our product candidates. Regulatory approval of a product candidate is not guaranteed, and the approval process is expensive, uncertain and lengthy.

We cannot commercialize our product candidates until the appropriate regulatory authorities, such as the FDA, have reviewed and approved the product candidate. The regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval for our product candidates. Additional delays may result if a product candidate is brought before an FDA advisory committee, which could recommend restrictions on approval or recommend non-approval of the product candidate. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical studies and the review process. As a result, we cannot predict when, if at all, we will receive any future revenue from commercialization of any of our product candidates. The FDA and foreign regulatory authorities have substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons, including the following:

- we may be unable to demonstrate to the satisfaction of regulatory authorities that a product candidate is safe and effective for any indication;
- regulatory authorities may not find the data from nonclinical studies and clinical studies sufficient or may differ in the interpretation of the data;
- regulatory authorities may require additional nonclinical or clinical studies;
- regulatory authorities might not approve our third-party manufacturers' processes or facilities for clinical or commercial product;

- regulatory authorities may change their approval policies or adopt new regulations;
- regulatory authorities may disagree with the design or implementation of our clinical studies;
- regulatory authorities may not accept clinical data from studies that are conducted in countries where the standard of care is potentially different from the jurisdiction of that regulatory authority;
- the results of clinical studies may not meet the level of statistical significance required by regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks; and
- the data collection from clinical studies of our product candidates may not be sufficient to support the submission of a new drug application (NDA), marketing authorization or other equivalent submission, or to obtain regulatory approval in the United States or elsewhere.

In addition, events raising questions about the safety of certain marketed pharmaceuticals may result in increased caution by the FDA and other regulatory authorities in reviewing new pharmaceuticals based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals.

Even if we obtain regulatory approval for our product candidates, we will still face extensive regulatory requirements and our products may face future development and regulatory difficulties.

Even if we obtain regulatory approval in the United States, the FDA may still impose significant restrictions on the indicated uses or marketing of our products or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. Our products would be subject to additional ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping and reporting of safety and other post-market information. The holder of an approved NDA is obligated to monitor and report AEs and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. Furthermore, promotional materials must be approved by the FDA prior to use for any drug receiving accelerated approval.

In addition, manufacturers of drug products and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current Good Manufacturing Practices (cGMP), and adherence to commitments made in the NDA. If we, or a regulatory agency, discover previously unknown problems with a product, such as quality issues or AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requesting recall or withdrawal of the product from the market or suspension of manufacturing.

If we, or our third-party contractors, fail to comply with applicable regulatory requirements following approval of our product candidate, a regulatory agency may:

- issue an untitled or warning letter asserting violation of the law;
- seek an injunction or impose civil or criminal penalties up to and including imprisonment or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or supplements to an NDA; or
- request recall and/or seize product.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and inhibit our ability to generate revenues.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. If we are found to have improperly promoted our products for off-label uses, we may become subject to significant fines and other liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. 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 our product candidates, physicians may nevertheless prescribe such products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant government fines and other related liability. For example, the federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA also has requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Even if we obtain FDA approval for our product candidates in the United States, we may never obtain approval for or commercialize our product candidates outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials that could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be unrealized.

Coverage and adequate reimbursement may not be available for our future products, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any products that we commercialize will depend in part on the extent to which coverage and adequate reimbursement will be available from third-party payers, including government health administration authorities, managed care organizations and private health insurers. Third-party payers decide which therapies they will pay for and establish reimbursement levels. Third-party payers in the United States often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any products that we develop will be made on a payer-by-payer basis. One payer's determination to provide coverage for a drug does not assure that other payers will also provide coverage and adequate reimbursement for the drug. Additionally, a third-party payer's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Third-party payers are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We cannot be sure that coverage and reimbursement in the United States or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Our relationships with health care professionals, customers and payors may be subject to applicable anti-kickback, fraud and abuse and other health care laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Health care professionals and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, third-party payors and customers may expose us to broadly applicable fraud and abuse and other health care laws and regulations that may constrain the business or financial arrangements and relationships through which we research, as well as market, sell and distribute our products. Restrictions under applicable federal and state health care laws and regulations, include the federal Anti-Kickback Statute, the federal False Claims Act, Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, the federal false statements statute, the federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or PPACA, commonly referred to as the Physician Payments Sunshine Act, and analogous state laws and regulations, such as state anti-kickback and false claims laws.

Efforts to ensure that our business arrangements with third parties will comply with applicable health care laws and regulations will involve 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 health care 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 civil, criminal and administrative penalties, damages, fines, disgorgement, exclusion from government funded health care programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded health care programs.

Current laws and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain marketing approval.

For example, the PPACA was enacted to broaden access to health insurance, reduce or constrain the growth of health care spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Since its enactment there have been judicial and Congressional challenges to certain aspects of the PPACA as well as efforts to repeal or replace certain aspects of the PPACA. For example, Congress considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the PPACA. It is unclear how litigation, and the healthcare reform measures of the Biden administration will impact the PPACA and our business.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. In addition, there have been several recent congressional inquiries, proposed bills and other proposals designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products including instituting reference pricing. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. However, it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. 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 are not sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. Further, it is possible that additional governmental action is taken in response to the COVID-19 situation.

Risks Related to COVID-19

Our business may be adversely affected by the ongoing COVID-19 situation.

While the COVID-19 outbreak has not materially adversely affect our business operations, economic and health conditions in the United States and across most of the globe have continued to change. As a result of COVID-19, we have experienced and may continue to experience disruptions that could impact aspects of our business, including our progress towards the completion of our clinical studies and other drug development activities. Possible future disruptions are currently difficult to foresee and include, but are not limited to, potential risk areas as noted below:

- We are currently managing clinical trials and expect to begin clinical trials in geographies that are affected by COVID-19. While we have not experienced material impacts to our clinical activities to date, we are observing impacts due to COVID-19, including reluctance of subjects to enroll in clinical studies, restrictions impacting study personnel and trial participants, personnel shortages at clinical sites and operations and facility restrictions impacting trial operations. We believe that COVID-19 will have a continuing impact on various aspects of our clinical activities in the future. For example, pandemic-related reluctance or restrictions, including curtailment of activities, could reduce or slow the rate of patient enrollment in our clinical trials, and impair the ability to efficiently treat patients at investigator sites. Additionally, our employees, representatives from our clinical research organization partners, and study investigators may be required to delay, or alter, their approach to complete work on our trials.

- We have moved to a hybrid model of operations, with most employees working from our office for a portion of the week and working remotely for the rest of the week.
- Our continuing reliance on personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. In addition, this could increase our cyber-security and data privacy risks, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations, or delay necessary interactions with regulators, contract manufacturers, contract research organizations, clinical trial sites, and other important agencies and contractors, which could result in increased costs to us.
- The United States Food and Drug Administration (FDA), comparable foreign regulatory agencies, and ethics boards may experience operational interruptions or delays, which could impact timelines for regulatory meetings, submissions, trial initiations, and regulatory approvals.

The emergence of additional COVID-19 variants may also continue to affect the impact of the situation. The extent to which COVID-19 may impact our business, including our preclinical, clinical and associated drug development activities, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of COVID-19 and variants to COVID-19 that continue to arise and their relative transmissibility and virulence, as well as business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

Risks Related to Our Reliance on Third Parties

We rely on third-party manufacturers to produce our preclinical and clinical drug supplies, and we intend to rely on third parties to produce commercial supplies of any approved products.

We do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing. We currently rely on third-party manufacturers for supply of our preclinical and clinical drug supplies. We expect that in the future we will continue to rely on such manufacturers for drug supplies that will be used in clinical trials of our product candidates, and for commercialization of any of our product candidates that receive regulatory approval.

The facilities used by our contract manufacturers to manufacture the approved product must be approved by the FDA pursuant to inspections that will be conducted only after we submit an NDA to the FDA, if at all. A representative from the European Medicines Agency (EMA) or another regulatory authority may also require inspection and approval of such contract manufacturing facilities. We are completely dependent on our contract manufacturing partners for compliance with the FDA's requirements for manufacture of finished pharmaceutical products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA's strict regulatory requirements of safety, purity and potency, we will not be able to secure and/or maintain FDA approval for our product candidates. In addition, we have no direct control over the ability of the contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If our contract manufacturers cannot meet FDA standards, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our products. No assurance can be given that our manufacturers can continue to make clinical and commercial supplies of product candidates, at an appropriate scale and cost to make it commercially feasible.

In addition, we do not have the capability to package and distribute finished products to pharmacies and other customers. If we receive marketing approval from the FDA, we intend to sell pharmaceutical product packaged and distributed by one or more pharmaceutical product packagers/distributors. Although we have entered into agreements with our current contract manufacturers and packager/distributor for clinical trial material, we will need to enter into commercial agreements with contract manufacturers and with one or more pharmaceutical product packagers/distributors to ensure proper supply chain management once we are authorized to make commercial sales of our product candidates. However, we may be unable to maintain agreements or negotiate commercial supply agreements on commercially reasonable terms with contract manufacturers and pharmaceutical product packagers/distributors, which could delay our ability to launch commercial sales and/or have a material adverse impact upon our business.

We rely on limited sources of supply for our product candidates, and any disruption in the chain of supply may cause delay in developing and commercializing for each product candidate.

If supply from an approved vendor is interrupted, there could be a significant disruption in commercial supply of our products. An alternative vendor would need to be qualified through a supplemental registration, which would be expensive, time consuming and could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if a new drug substance or drug product supplier is relied upon for commercial production. These factors could cause the delay of clinical

trials, regulatory submissions, required approvals or commercialization of our products, and cause us to incur additional costs. Furthermore, if our suppliers fail to deliver the required commercial quantities of active pharmaceutical ingredient on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, the supply chain for our products may be delayed, which could inhibit our ability to generate revenues.

Manufacturing issues may arise that could increase product and regulatory approval costs or delay commercialization of our products.

As the manufacturing processes are scaled up they may reveal manufacturing challenges or previously unknown impurities that could require resolution in order to proceed with our planned clinical trials and obtain regulatory approval for the commercial marketing of our products. In the future, we may identify manufacturing issues or impurities that could result in delays in the clinical program and regulatory approval for our products, increases in our operating expenses, or failure to obtain or maintain approval for our products.

Our reliance on third-party manufacturers entails risks, including the following:

- the inability to meet our product specifications, including product formulation, and quality requirements consistently;
- a delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues, including those related toscale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- a failure to comply with cGMP and similar quality standards;
- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- the reliance on a limited number of sources, and in some cases, single sources for key materials, such that if we are unable to secure a sufficient supply of these key materials, we will be unable to manufacture and sell our products in a timely fashion, in sufficient quantities or under acceptable terms;
- the lack of qualified backup suppliers for those materials that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier;
- disruption of the distribution of chemical supplies between the U.K. and E.U. due to Brexit;
- carrier disruptions or increased costs that are beyond our control; and
- the failure to deliver our products under specified storage conditions and in a timely manner.

Any of these events could lead to delays in any clinical study we may undertake, failure to obtain regulatory approval or impact our ability to successfully commercialize our products. Some of these events could be the basis for FDA or other regulatory authorities' action, including injunction, recall, seizure, or total or partial suspension of production.

We rely on third parties to conduct, supervise and monitor our clinical studies, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We rely on contract service providers (CSPs), including clinical research organizations, clinical trial sites, central laboratories and other service providers to ensure the proper and timely conduct of our clinical trials. While we have agreements governing their activities, we have limited influence over their actual performance. We have relied and plan to continue to rely upon CSPs to monitor and manage data for clinical programs for our product candidates, as well as the execution of nonclinical studies. We control only certain aspects of our CSPs' activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CSPs does not relieve us of our regulatory responsibilities.

We and our CSPs are required to comply with the FDA's guidance, which follows the International Council on Harmonisation Good Clinical Practice (ICH GCP), which are regulations and guidelines enforced by the FDA for all of our product candidates in clinical development. The FDA enforces the ICH GCP through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CSPs fail to comply with the ICH GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. Our CSPs are not our employees, and we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and nonclinical programs. These CSPs may also have relationships with other entities, including our competitors, for whom they may also be conducting clinical studies, or other drug development activities that could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our confidential information, including our intellectual property, by CSPs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology, among other things. If our CSPs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any 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 our product candidates. As a result, our financial results and the commercial prospects for our product candidates that we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

Risks Related to Commercialization of Our Product Candidates

The commercial success of any product will depend upon the acceptance of these products by the medical community, including physicians, patients and health care payors.

If any of our product candidates receive marketing approval, they may nonetheless be unable to gain sufficient market acceptance by physicians, patients, health care payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any of our products will depend on a number of factors, including the following:

- demonstration of clinical safety and efficacy in our clinical trials;
- the risk/benefit profile of our products;
- the relative convenience, ease of administration and acceptance by physicians, patients and health care payors;
- the prevalence and severity of any side effects;
- the safety of products seen in a broader patient group, including its use outside the approved indications;
- limitations or warnings contained in the FDA and other regulatory authorities approved label for the relevant product;
- acceptance of the product by physicians, other health care providers and patients as a safe and effective treatment;
- the potential and perceived advantages of products over alternative treatments;
- the timing of market introduction of competitive products;
- pricing and cost-effectiveness;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- our ability to obtain formulary approval;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement, which may vary from country to country; and
- the effectiveness of our or any future collaborators' sales, marketing and distribution efforts.

If any of our product candidates is approved but does not achieve an adequate level of acceptance by physicians, patients and health care payors, we may not generate sufficient revenue and we may not become or remain profitable.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product, we may be unable to generate any revenue.

We currently do not have an organization for the sales, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. We may enter into strategic partnerships with third parties to commercialize our products.

If we are unable to successfully manage pre-commercialization activities, including but not limited to building our own sales force (or negotiate one or more strategic partnership(s) for the commercialization of our products) or establish marketing and distribution channels, we may be forced to delay the potential commercialization of the product, or reduce the scope of our sales or marketing activities. If we elect to increase our expenditures to fund commercialization activities ourselves, we will 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 will not be able to bring the product to market or generate product revenue.

If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. We will be competing with companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform sales and marketing functions, we may be unable to compete successfully against these more established companies.

In addition, there are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

If we obtain approval to commercialize any products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If our product candidates are approved for commercialization outside the United States, we expect that we will be subject to additional risks related to international operations, including the following:

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- differing payor reimbursement regimes, governmental payors or patientself-pay systems and price controls;
- 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 revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, pandemics, or natural disasters including earthquakes, typhoons, volcanic eruptions, floods and fires.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by both the European Union and many of the individual countries in Europe with which we would need to comply. Many U.S.-based biopharmaceutical companies have found the process of marketing their own products in Europe to be very challenging.

If our competitors develop and market products that are more effective, safer or less expensive than our own, our commercial opportunities will be negatively impacted.

The life sciences industry is highly competitive, and we face significant competition from other pharmaceutical, biopharmaceutical and biotechnology companies and possibly from academic institutions, government agencies and private and public research institutions that are researching, developing and marketing products designed to address diseases that we are seeking to treat. Our competitors generally have significantly greater financial, manufacturing, marketing and drug development resources. Large pharmaceutical companies, in particular, have extensive experience in the clinical testing of, obtaining regulatory approvals for, and marketing of, drugs. New developments, including the development of other pharmaceutical technologies and methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace.

These developments may render our product candidates obsolete or noncompetitive. Compared to us, potential competitors may have substantially greater:

- research and development resources, including personnel and technology;
- regulatory experience;
- experience in pharmaceutical development and commercialization;
- ability to negotiate competitive pricing and reimbursement with third-party payors;
- experience and expertise in the exploitation of intellectual property rights; and
- capital resources.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we do or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. The competitors may also develop products that are more effective, better tolerated, more useful and less costly than our products and they may also be more successful in manufacturing and marketing their products.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical studies, and will face an even greater risk if we sell our products commercially. An individual or a group of individuals may bring a liability claim against us if one of our product candidates causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in the following:

- decreased demand for our products;
- impairment to our business reputation;
- withdrawal of clinical study participants;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our products; and
- loss of revenues.

We carry product liability insurance for our clinical studies. Further, we intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for any of our product candidates. However, we may be unable to obtain this product liability insurance on commercially reasonable terms and with insurance coverage that will be adequate to satisfy any liability that may arise. On occasion, large judgments have been awarded in class action or individual lawsuits relating to marketed pharmaceuticals. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

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

The success of our business depends primarily upon our ability to identify, develop and commercialize product candidates. Because we have limited financial and managerial resources, we focus on specific product candidates for specific indications. 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. We may focus our efforts and resources on product candidates that ultimately prove to be unsuccessful.

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 advantageous for us to retain sole development and commercialization rights.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to our products and product candidates, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own, co-own or in-license may fail to result in issued patents with claims that cover the products in the United States or in other countries. If this were to occur, early generic competition could be expected against our products. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which if it exists could be used to invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, third parties may challenge their validity, enforceability, scope or ownership, which may result in such patents, or our rights to such patents, being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the patent applications we hold or license with respect to our product candidates fail to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us and threaten our ability to commercialize our products. We cannot offer any assurances about which, if any, patents will issue or whether any issued patents will be found invalid or unenforceable, will be challenged by third parties or will adequately protect our products. Further, if we encounter delays in development or regulatory approvals, the period of time during which we could market our products under patent protection could be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file any patent application related to our product candidates. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be started by a third party or instituted by us to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license it from the prevailing party, which may not be available on commercially reasonable terms or at all.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietaryknow-how that is not patentable, processes for which patents are difficult to enforce and other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we expect all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed, that such agreements provide adequate protection and will not be breached, that our trade secrets and other confidential proprietary information will not otherwise be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Further, the laws of some foreign countries do not protect patents and other proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property abroad. We may also fail to pursue or obtain patents and other intellectual property protection relating to our products and product candidates in all foreign countries.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts or otherwise affect our business.

Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter party re-examination proceedings before the United States Patent and Trademark Office (U.S. PTO) and its foreign counterparts. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. We have been involved in the past in legal proceedings alleging the misappropriation of trade secrets.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. 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. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist that might be enforced against our products or product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

We license certain key intellectual property from third parties, and the loss of our license rights could have a materially adverse effect on our business.

We are a party to a number of technology licenses that are important to our business and may enter into additional licenses in the future. For example, we rely on an exclusive license to certain patents and know-how from Janssen Pharmaceutical NV (Janssen NV), which include seladelpar and certain other PPARd compounds (the PPARd Products). Under the exclusive license with Janssen NV we have full control and responsibility over the research, development and registration of any PPARd Products and are required to use diligent efforts to conduct all such activities. If we fail to comply with our obligations under our agreement with Janssen NV, including our obligations to expend more than a de minimis amount of effort and resources on the research and/or development of at least one PPARd Product, to make any payment called for under the agreement, not to disclose anynon-exempt confidential information related to the agreement, or to use diligent efforts to promote, market and sell any PPARd Product under the agreement, such action would constitute a default under the agreement and Janssen NV may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license, including in the case of the Janssen NV license, seladelpar, which would have a materially adverse effect on our business.

We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is invalid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter-claims against us.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in a litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

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 during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

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

Periodic maintenance fees on any issued patent are due to be paid to the U.S. PTO and foreign patent agencies in several stages over the lifetime of the patent. The U.S. PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, 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. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors that control the prosecution and maintenance of our licensed patents fail to maintain the patents and patent applications covering our product candidates, we may lose our rights and our competitors might be able to enter the market, which would have a material adverse effect on our business.

Risks Related to Our Business Operations and Industry

Our business could be negatively affected as a result of the actions of activist or hostile stockholders.

Our business could be negatively affected as a result of stockholder activism, which could cause us to incur significant expense, hinder execution of our business strategy, and impact the trading value of our securities. For example, in April 2020, a stockholder filed a preliminary proxy statement containing proposed opposition to our preliminarily filed proxy statement, including a proposal to elect three new directors to our Board of Directors and a proposal not to increase to the number of shares of common stock authorized for issuance. While this proxy contest was subsequently suspended, stockholder activism could recur and requires significant time and attention by management and the Board of Directors, potentially interfering with our ability to execute our strategic plan. Stockholder activism could give rise to perceived uncertainties as to our future direction, adversely affect our relationships with key executives and business partners, and make it more difficult to attract and retain qualified personnel. Also, we may be required to incur significant legal fees and other expenses related to activist stockholder matters. Any of these impacts could materially and adversely affect our business and operating results. Further, the market price of our common stock could be subject to significant fluctuation or otherwise be adversely affected by stockholder activism.

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are dependent on principal members of our executive team. While we have entered into employment offer letters with each of our executive officers, any of them could leave our employment at any time, as all of our employees are “at will” employees. We do not maintain “key person” insurance for any of our executives or other employees. Recruiting and retaining other qualified employees for our business, including clinical, scientific, technical and sales and marketing personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. We also experience competition from universities, competitors and research institutions for the hiring of scientific and clinical personnel. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. In addition, failure of any of our clinical studies may make it more challenging to recruit and retain qualified personnel. If we are unable to successfully recruit key employees or replace key executives or key employees, it may adversely affect the progress of our research, development and commercialization objectives.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategies. Our consultants and advisors may be engaged by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us, which could also adversely affect the progress of our research, development and commercialization objectives.

As we continue to build our clinical and drug development operations, we will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As we continue to build our clinical and drug development programs, we are expanding our employee base to increase our managerial, clinical, scientific, sales and marketing and other operational teams. Such growth imposes additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a greater amount of attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among current employees. Our expected growth could require greater capital expenditures and may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to create value and/or generate revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to develop and commercialize seladelpar and other potential product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Significant disruptions of information technology systems or breaches of data security could materially adversely affect our business, results of operations and financial condition.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business, particularly in view of our current remote work schedule. In the ordinary course of our business, we collect, store and transmit confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have established physical, electronic and organizational measures to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization.

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. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems and security vulnerabilities could be significant, and our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event is to occur and cause interruptions in our operations or our vendors, it may result in a material disruption of our product development programs and our reputation could be materially damaged. We could also be exposed to a risk of loss or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

Changes in and failures to comply with United States and foreign privacy and data protection laws, regulations and standards may adversely affect our business, operations and consolidated financial performance.

We are subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, retention, and security of personal data, such as information that we collect about patients and healthcare providers in connection with clinical trials in the United States and abroad. The global data protection landscape is rapidly evolving, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, affect our or our vendors' ability to operate in certain jurisdictions or to collect, store, transfer, use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. In many jurisdictions, enforcement actions and consequences for noncompliance are rising.

In the United States, HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. In the event that we are subject to HIPAA or other United States privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. Many countries in these regions have established or are in the process of establishing privacy and data security legal frameworks with which we, our customers, or our vendors must comply. For example, the EU has adopted the General Data Protection Regulation (EU) 2016/679, or GDPR, which went into effect in May 2018 and includes strict requirements for processing the personal information of EU subjects, including clinical trial data. The GDPR has increased compliance burdens on us, including by mandating potentially burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and process information about them. The processing of sensitive personal data, such as physical health condition, has imposed heightened compliance burdens under the GDPR and is a topic of active interest among foreign regulators. In addition, the GDPR provides for robust regulatory enforcement and fines for a noncompliant company. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

Risks Relating to Owning Our Common Stock

An active trading market for our common stock may not continue and the market price for our common stock may decline in value.

Our common stock was formerly listed on the Nasdaq Capital Market and since the second quarter of 2018 it has been trading on the Nasdaq Global Select Market under the symbol “CBAY”. The historical trading prices of our common stock on the Nasdaq Capital Market and the Nasdaq Global Select Market may not be indicative of the price levels at which our common stock will trade in the future, and we cannot predict the extent to which investor interest in us will continue to support an active public trading market for our common stock or how liquid will be that public market.

Our stock price is volatile, and our stockholders’ investment in our stock could decline in value.

The historical trading price of our common stock has been volatile. Our stock price may continue to be subject to wide fluctuations in response to a variety of factors, including:

- delays in completing the RESPONSE clinical trial and our other clinical trials;
- adverse, delayed or inconclusive results in our clinical trials, particularly our RESPONSE clinical trial;
- adverse or inconclusive results or delays in preclinical testing;
- inability to obtain additional funding;
- any delay in filing an Investigational New Drug (IND) application or NDA for any of our future product candidates and any adverse development or perceived adverse development with respect to the FDA’s review of an IND or NDA;
- failure to enter into new collaborations;
- failure by us or our licensors to prosecute, maintain or enforce our intellectual property rights;
- failure to successfully develop and commercialize our future product candidates;
- changes in laws or regulations applicable to future products;
- changes in the structure of health care payment systems;
- inability to obtain adequate product supply for our product candidates or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we may provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;

- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- announcements of significant or potential equity or debt sales by us;
- announcements of clinical trial plans or results by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future; and
- trading volume of our common stock.

In addition, companies trading in the stock market in general 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.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

Significant additional capital may be needed in the future to continue our product development efforts in current and future clinical trials and operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If in the future we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. These sales may also result in new investors gaining rights superior to our existing stockholders. Pursuant to our equity incentive plans, we are authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares available for future grant under our equity incentive plans as of March 31, 2023 was 3,067,331 shares.

Anti-takeover provisions in our charter documents and under 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.

Provisions in our certificate of incorporation and our bylaws may delay or prevent an acquisition of us. In addition, 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, who are responsible for appointing the members of our management team. In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits, with some exceptions, stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. Finally, our charter documents establish advance notice requirements for nominations for election to our board of directors and for proposing matters that can be acted upon at stockholder meetings. Although we believe these provisions together provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders.

General Risks

We do not anticipate paying cash dividends, and accordingly, stockholders must rely on stock appreciation for any return on their investment.

We do not anticipate paying cash dividends in the future. As a result, only appreciation of the price of our common stock, which may never occur, will provide a return to stockholders. Investors seeking cash dividends should not invest in our common stock.

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

Our share price is 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. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management’s attention from other business concerns, which could seriously harm our business.

Item 6. Exhibits

Exhibit No.	Description of Document	Incorporation by Reference			
		Form	Sec. File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation.	10/A	000-55021	3.1	10/17/2013
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation.	8-K	000-36500	3.1	6/26/2020
3.3	Amended and Restated By-Laws.	10/A	000-55021	3.2	10/17/2013
4.1	Reference is made to Exhibits 3.1, 3.2 and 3.3.				
10.1	Notice of Resignation and Transition Agreement, dated February 17, 2023, between the registrant and Dennis Kim.	8-K	001-36500	10.1	2/23/2023
10.2	Collaboration and License Agreement, dated January 6, 2023, between CymaBay Therapeutics, Inc. and Kaken Pharmaceutical Co., Ltd.	10-K	001-36500	10.12	3/23/2023
31.1+	Certification of President and Chief Executive Officer (Principal Executive Officer) pursuant to Rule 13-a-14(a) or Rule 15(d)-14(a) of the Exchange Act.				
31.2+	Certification of Vice President, Finance (Principal Financial Officer) pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Exchange Act.				
32.1++	Certification of President and Chief Executive Officer (Principal Executive Officer) and Vice President, Finance (Principal 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				
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 Document				
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in exhibit 101)				

\+ Filed herewith.
++ Furnished herewith.
\# Certain portions of this exhibit have been omitted because the omitted portions are both not material and is the type of information that CymaBay treats as private or confidential.

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.

CYMABAY THERAPEUTICS, INC.

By: /s/ Sujal Shah
Sujal Shah
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 15, 2023

By: /s/ Daniel Menold
Daniel Menold
Vice President, Finance
(Principal Financial and Accounting Officer)

Date: May 15, 2023

Exhibit 31.1

CERTIFICATIONS

I, Sujal Shah, certify that:

1. I have reviewed this Form 10-Q of CymaBay Therapeutics, Inc.;

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: May 15, 2023

/s/ Sujal Shah
Sujal Shah
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Daniel Menold, certify that:

1. I have reviewed this Form 10-Q of CymaBay Therapeutics, Inc.;

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules13a-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; an

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

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

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

Date: May 15, 2023

/s/ Daniel Menold
Daniel Menold
Vice President, Finance
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION

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), each of Sujal Shah, President and Chief Executive Officer, and Daniel Menold, Vice President, Finance of CymaBay Therapeutics, Inc. (the "Company"), 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.

In Witness Whereof, the undersigned has set his hand hereto as of May 15, 2023.

/s/ Sujal Shah
Sujal Shah
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Daniel Menold
Daniel Menold
Vice President, Finance
(Principal Financial and Accounting 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 CymaBay Therapeutics, 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.