
**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, 2021**

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
(State or other jurisdiction of
incorporation or organization)

94-3103561
(I.R.S. Employer
Identification No.)

7575 Gateway Blvd, Suite 110
Newark, CA
(Address of principal executive offices)

94560
(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, a non-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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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, 2021, there were 68,995,772 shares of the registrant's common stock outstanding.



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

TABLE OF CONTENTS

	<u>Page</u>
PART I	<u>FINANCIAL INFORMATION</u>
Item 1.	<u>Financial Statements</u>
	<u>Condensed Consolidated Balance Sheets at March 31, 2021 and December 31, 2020 (unaudited)</u>
	<u>Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three Months Ended March 31, 2021 and 2020 (unaudited)</u>
	<u>Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2021 and 2020 (unaudited)</u>
	<u>Condensed Consolidated Statements of Stockholders' Equity for the Three Months Ended March 31, 2021 and 2020 (unaudited)</u>
	<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>
Item 4.	<u>Controls and Procedures</u>
PART II	<u>OTHER INFORMATION</u>
Item 1.	<u>Legal Proceedings</u>
Item 1A.	<u>Risk Factors</u>
Item 6.	<u>Exhibits</u>
<u>Signatures</u>	48

[Table of Contents](#)**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements**

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

	<u>March 31,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 43,326	\$ 28,193
Marketable securities	82,132	118,130
Accrued interest receivable	265	277
Prepaid research and development expenses	5,631	2,221
Other prepaid expenses and current assets	1,919	2,764
Total current assets	133,273	151,585
Property and equipment, net	1,690	1,761
Operating lease right-of-use asset	273	272
Other assets	1,446	207
Total assets	<u>\$ 136,682</u>	<u>\$ 153,825</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,606	\$ 231
Accrued research and development expenses	3,294	4,698
Other accrued liabilities	3,009	4,928
Total current liabilities	7,909	9,857
Long-term portion of operating lease liability	1,127	1,262
Total liabilities	9,036	11,119
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; 68,946,092 and 68,946,092 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	7	7
Additional paid-in capital	822,054	819,549
Accumulated other comprehensive (loss) income	(6)	8
Accumulated deficit	(694,409)	(676,858)
Total stockholders' equity	127,646	142,706
Total liabilities and stockholders' equity	<u>\$ 136,682</u>	<u>\$ 153,825</u>

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,	
	2021	2020
Operating expenses:		
Research and development	\$ 12,382	\$ 9,509
General and administrative	5,236	4,418
Total operating expenses	17,618	13,927
Loss from operations	(17,618)	(13,927)
Interest income	67	839
Net loss	<u>\$ (17,551)</u>	<u>\$ (13,088)</u>
Other comprehensive loss:		
Unrealized loss on marketable securities	(14)	(210)
Total other comprehensive loss	(14)	(210)
Comprehensive loss	<u>\$ (17,565)</u>	<u>\$ (13,298)</u>
Basic and diluted net loss per common share	\$ (0.25)	\$ (0.19)
Weighted average common shares outstanding used to calculate basic and diluted net loss per common share	68,946,092	68,882,459

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,	
	2021	2020
Operating activities		
Net loss	\$(17,551)	\$(13,088)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	164	153
Stock-based compensation expense	2,505	1,998
Net accretion and amortization of investments in marketable securities	196	(205)
Changes in assets and liabilities:		
Interest receivable and other current assets	299	310
Prepaid research and development expenses and other prepaid assets	(2,852)	1,951
Other assets	(1,239)	—
Accounts payable	1,375	(1,290)
Accrued liabilities	(3,458)	(4,537)
Net cash used in operating activities	(20,561)	(14,708)
Investing activities		
Purchases of property and equipment	(94)	—
Purchases of marketable securities	(18,212)	(65,503)
Proceeds from maturities of marketable securities	54,000	112,136
Net cash provided by investing activities	35,694	46,633
Financing activities		
Cash provided by financing activities	—	—
Net increase in cash and cash equivalents	15,133	31,925
Cash and cash equivalents at beginning of period	28,193	24,869
Cash and cash equivalents at end of period	<u>\$ 43,326</u>	<u>\$ 56,794</u>
Supplemental disclosure		
Cash paid for amounts included in the measurement of lease liabilities	\$ 166	\$ 161

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended March 31, 2021					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances as of December 31, 2020	68,946,092	\$ 7	\$ 819,549	\$ 8	\$ (676,858)	\$ 142,706
Stock-based compensation expense	—	—	2,505	—	—	2,505
Net loss	—	—	—	—	(17,551)	(17,551)
Net unrealized loss on marketable securities	—	—	—	(14)	—	(14)
Balances as of March 31, 2021	<u>68,946,092</u>	<u>\$ 7</u>	<u>\$ 822,054</u>	<u>\$ (6)</u>	<u>\$ (694,409)</u>	<u>\$ 127,646</u>

	Three Months Ended March 31, 2020					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances as of December 31, 2019	68,882,459	\$ 7	\$ 812,133	\$ 80	\$ (625,872)	\$ 186,348
Stock-based compensation expense	—	—	1,998	—	—	1,998
Net loss	—	—	—	—	(13,088)	(13,088)
Net unrealized loss on marketable securities	—	—	—	(210)	—	(210)
Balances as of March 31, 2020	<u>68,882,459</u>	<u>\$ 7</u>	<u>\$ 814,131</u>	<u>\$ (130)</u>	<u>\$ (638,960)</u>	<u>\$ 175,048</u>

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 liver diseases, including primary biliary cholangitis (PBC) and nonalcoholic steatohepatitis (NASH). 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, 2021, the Company incurred a net loss of \$17.6 million and used \$20.6 million of cash in operations. At March 31, 2021, the Company had an accumulated deficit of \$694.4 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, 2021, the Company had cash, cash equivalents and marketable securities totaling \$125.5 million. As the Company continues to advance its clinical studies of seladelpar, the Company believes these funds are sufficient to fund the Company's current operating plan into mid-2022. 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 resulting from the global novel coronavirus disease (COVID-19) pandemic or other factors could also adversely impact the Company's 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, 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.

[Table of Contents](#)

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, 2020, which is contained in the Company's Annual Report on Form 10-K as filed with the SEC on March 25, 2021. The results for the three months ended March 31, 2021 are not necessarily indicative of results to be expected for the entire year ending December 31, 2021 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.

Fair Value of Financial Instruments

The Company's financial instruments during the periods reported consist of cash and cash equivalents, marketable securities, accrued interest receivable, prepaid research and development expenses, other prepaid expenses and current assets, accounts payable, and accrued expenses. Fair value estimates of these instruments are made at a specific point in time based on relevant market information. These estimates may be subjective in nature and involve uncertainties and matters of significant judgment. The carrying amounts of financial instruments such as cash and cash equivalents, receivables, prepaid expenses, other current assets, accounts payable, and accrued expenses approximate the related fair values due to the short maturities of these instruments.

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 maximizes 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 market activity), which requires the reporting entity to develop its own valuation techniques and assumptions.

Table of Contents

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

	As of March 31, 2021			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$38,460	\$ —	\$ —	\$ 38,460
Total cash equivalents	38,460	—	—	38,460
Marketable securities:				
U.S. treasury securities	—	8,000	—	8,000
U.S. and foreign commercial paper	—	33,475	—	33,475
U.S. and foreign corporate debt securities	—	23,677	—	23,677
Asset-backed securities	—	13,978	—	13,978
Supranational debt securities	—	3,002	—	3,002
Total marketable securities	—	82,132	—	82,132
Total assets measured at fair value	\$38,460	\$ 82,132	\$ —	\$120,592

	As of December 31, 2020			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$22,415	\$ —	\$ —	\$ 22,415
U.S. commercial paper	—	—	—	—
Total cash equivalents	22,415	—	—	22,415
Marketable securities:				
U.S. treasury securities	—	15,499	—	15,499
U.S. and foreign commercial paper	—	38,561	—	38,561
U.S. and foreign corporate debt securities	—	29,189	—	29,189
U.S. agency securities	—	23,994	—	23,994
Asset-backed securities	—	7,885	—	7,885
Supranational debt securities	—	3,002	—	3,002
Total marketable securities	—	118,130	—	118,130
Total assets measured at fair value	\$22,415	\$118,130	\$ —	\$140,545

The Company estimates the fair value of its money market funds, corporate debt, asset-backed securities, commercial paper, U.S. treasury and agency securities, and supranational debt securities by taking into consideration valuations 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.

[Table of Contents](#)

Cash, Cash Equivalents, and Marketable Securities

The Company considers all highly liquid investments with an original maturity of 90 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 that are classified in Level 1 and Level 2 of the fair value hierarchy. These securities consist primarily of corporate debt, commercial paper, asset-backed securities, U.S. treasury and agency 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 of the balance sheet date.

Realized gains and losses from the sale of marketable securities, if any, are calculated using the specific-identification method. Realized gains and losses and declines in value judged to be other-than-temporary are included in interest income or expense in the condensed consolidated statements of operations and comprehensive loss. 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 impairment charges on its marketable securities related to other-than-temporary declines in market value. In determining whether a decline in market value is other-than-temporary, various factors are considered, including the cause, duration of time and severity of the impairment, 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.

For our investments as of March 31, 2021 and December 31, 2020, there were no material unrealized gains or losses.

Concentrations 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 an 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.

Other Risks and Uncertainties

In March 2020, the World Health Organization declared the global novel coronavirus disease (COVID-19) outbreak a pandemic. To date, the Company’s operations have not been significantly impacted by the COVID-19 outbreak. However, the Company cannot at this time predict the specific extent, duration, or full impact that the COVID-19 outbreak will have on its condensed consolidated financial condition and operations. The impact of the COVID-19 coronavirus outbreak on the financial performance of the Company will depend on future developments, including the duration and spread of the outbreak and related governmental advisories and restrictions. 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, the Company’s results may be adversely affected.

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.

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.

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 outstanding equivalents during the period. Diluted net loss per share of common stock is calculated as the weighted average number of shares of common stock outstanding adjusted to include the assumed exercises of stock options, if dilutive.

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,	
	2021	2020
Numerator:		
Net loss	\$ (17,551)	\$ (13,088)
Denominator:		
Weighted average number of common stock shares outstanding	68,946,092	68,882,459
Net loss per share	<u>\$ (0.25)</u>	<u>\$ (0.19)</u>

Table of Contents

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

	Three Months Ended	
	March 31,	
	2021	2020
Common stock options	10,052	6,117
Incentive awards	101	101
Total	<u>10,153</u>	<u>6,218</u>

Recently Adopted Accounting Pronouncements

ASU 2019-12

In December 2019, the FASB issued ASU2019-12, Income Taxes (Topic 740): *Simplifying the Accounting for Income Taxes*, which removes certain exceptions to the general principles in Topic 740 related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The guidance became effective for the Company on January 1, 2021. The adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements and related disclosures for the three months ended March 31, 2021.

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 intends to adopt the standard on January 1, 2023 and are currently assessing potential effects of the guidance prior to the adoption date.

3. Other Accrued Liabilities

Other accrued liabilities consist of (in thousands):

	March 31, 2021	December 31, 2020
Accrued compensation	\$ 1,504	\$ 3,769
Accrued professional fees and other	1,003	677
Current portion of operating lease liability	502	482
Total other accrued liabilities	<u>\$ 3,009</u>	<u>\$ 4,928</u>

4. Collaboration and License Agreements

Janssen Pharmaceutical NV and Janssen Pharmaceuticals, Inc.

In June 2006, the Company entered into an exclusive, worldwide, royalty-bearing license to seladelpar and certain other PPAR α compounds (the PPAR α Products) with Janssen Pharmaceutical NV (Janssen NV), with the right to grant sublicenses to third parties to make, use and sell such PPAR α Products. Under the terms of the agreement, the Company has full control and responsibility over the research, development and registration of any PPAR α Products and is required to use diligent efforts to conduct all such activities. Janssen NV has the sole responsibility for the preparation, filing, prosecution, maintenance of, and defense of the patents with respect to, the PPAR α Products. Janssen NV has a right of first negotiation under the agreement to license the PPAR α Products from the Company in the event that the Company elects to seek a third party corporate partner for the research, development, promotion, and/or commercialization of such PPAR α Products. Under the terms of the agreement Janssen NV is entitled to receive up to an 8.0% royalty on net sales of PPAR α Products. No amounts were incurred or accrued for this agreement as of and for the three months ended March 31, 2021 and 2020.

DiaTex, Inc.

In June 1998, the Company entered into a license agreement with DiaTex, Inc. (DiaTex) relating to products containing halofenate, its enantiomers, derivatives, and analogs (the licensed products). The license agreement provides that DiaTex and the Company are joint owners of all the patents and patent applications covering the licensed products and methods of producing or using such compounds, as well as certain other know-how (the covered IP). As part of the license agreement, the Company received an exclusive worldwide license, including as to DiaTex, to use the covered IP to develop and commercialize the licensed products. The Company also retained the right to sub-license the covered IP. The license agreement contains a requirement to make additional payments for development achievements and royalty payments on any sales of licensed products containing arhalofenate. In December 2016, the agreement was amended by the parties to change the timing of a specified development milestone. No development payments were made or became due as of and for the three months ended March 31, 2021 and 2020 and no royalties have been paid to date.

5. Stock Plans and Stock-Based Compensation

Stock Plans

As permitted under the provisions of the Company's 2013 Equity Incentive Plan (the 2013 Plan), the Board of Directors reduced the automatic increase in the share reserve from 5% to 4% of common shares outstanding as of December 31, 2020, thereby adding an additional 2,757,843 shares to 2013 Plan share reserve on January 1, 2021. As of March 31, 2021, there were 1,684,439 shares available for grant under the 2013 Plan and an additional 750,000 shares available under the 2020 New Hire Plan (the 2020 Plan), for a total of 2,434,439 shares available for grant under both plans as of March 31, 2021. During the three months ended March 31, 2021, the Company granted 1,312,216 stock options, which primarily related to its option grants issued to employees.

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,	
	2021	2020
Research and development	\$ 1,077	\$ 444
General and administrative	1,428	1,554
Total stock-based compensation expense	<u>\$ 2,505</u>	<u>\$ 1,998</u>

6. 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 elafibanor in patients with primary biliary cholangitis. An Amended Complaint was filed on April 16, 2021 with substantially the same allegations. Genfit seeks 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 has not yet filed its Reply to the Amended Complaint. The Company intends to defend itself vigorously. While the outcome of any litigation is inherently uncertain, based on currently available information, management does not currently believe a loss associated with this matter is probable, nor is any amount reasonably estimable, and accordingly no amounts have been recorded or disclosed in the financial statements as of and for the quarter ended March 31, 2021.

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

Operating results for the three months ended March 31, 2021 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, including whether we may resume clinical testing, and the timing of results thereof; regulatory submissions and approvals; the impact of the COVID-19 pandemic 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.

Overview

CymaBay Therapeutics, Inc. 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.

Our lead product candidate, seladelpar, is a potent and selective agonist of peroxisome proliferator activated receptor delta (PPAR δ), 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 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; and
- nonalcoholic steatohepatitis (NASH), a prevalent and serious chronic liver disease caused by excessive fat accumulation in the liver that results in inflammation and cellular injury that can progress to fibrosis and cirrhosis, and potentially liver failure and death.

In late 2019, we terminated our NASH Phase 2b study and our ongoing PBC studies. The decision to halt development of seladelpar was based on initial histological observations in the NASH Phase 2b study that were observed in the first blinded tranche of liver biopsies in the trial. These observations were characterized by an interface hepatitis presentation, with or without biliary injury. Although these patients had stable or improving biochemical markers of liver disease, the decision to halt development was based on a need to understand the significance of the observations, and possible impact on patients, before dosing additional patients with seladelpar. The U.S. Food and Drug Administration (FDA) agreed with this decision and subsequently placed a formal clinical hold on seladelpar. Thereafter, in December 2019, we announced a restructuring plan to reduce our workforce by approximately 60% to control our operating costs, and we commenced a process to evaluate strategic alternatives to maximize stockholder value, pending further investigation of the histological observations. In May 2020, an independent expert panel completed a review of the findings and unanimously concluded that the data in aggregate did not support liver injury related to seladelpar. We subsequently discussed the data, the panel’s conclusions, and other matters with the FDA and in July 2020, the FDA lifted the clinical hold, thereby permitting us to reinstate clinical development of seladelpar. Specifically, we made the strategic decision to refocus our strategy primarily on clinical development of seladelpar in PBC and to explore the potential to partner seladelpar in NASH in a combination study with other complimentary agents. In addition, we are evaluating opportunities to develop other internal programs and possibly acquire or in-license new compounds or programs.

Seladelpar

Primary Biliary Cholangitis (PBC)

Following the decision to reinstate clinical development of seladelpar, in late 2020, we commenced startup and site feasibility activities for RESPONSE, a new global Phase 3 registration study to evaluate seladelpar in patients with PBC. The Phase 3 study is a 52-week, placebo-controlled, randomized, global, registration study evaluating the safety and efficacy of seladelpar in patients with PBC. The study is intended to enroll 180 patients, who have an inadequate response to, or intolerance to, ursodeoxycholic acid, in a 2:1 randomization to oral, once daily seladelpar 10 mg or placebo. The primary outcome measure will be the responder rate at 52 weeks. A responder is defined as a patient who achieves an alkaline phosphatase 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 alkaline phosphatase at 52 weeks and the level of pruritus at six months for patients with moderate to severe pruritus at baseline assessed by a numerical rating scale recorded with an electronic diary.

In addition to RESPONSE we also commenced startup activities in late 2020 for ASSURE, a new long-term safety study, which 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 in the future.

Previously, in October 2018, we commenced enrollment of ENHANCE, a global Phase 3 registration study to evaluate seladelpar in patients with PBC and in October 2019, the trial was fully enrolled with 265 patients, but we terminated the trial early in December 2019 after the seladelpar program was placed on clinical hold. In August 2020, we shared data accumulated through trial termination for ENHANCE, which we believe demonstrated seladelpar to be safe, well-tolerated, and efficacious in patients with PBC.

Nonalcoholic Steatohepatitis (NASH)

In May 2018, we initiated a randomized, placebo-controlled Phase 2b proof-of-concept study to evaluate seladelpar at three doses in biopsy-proven NASH. The primary efficacy outcome is the change from baseline in liver fat content at 12 weeks measured by magnetic resonance imaging using the proton density fat fraction method (MRI-PDFF). The study also included pathology assessments of liver biopsy samples at baseline and at 52 weeks to examine the potential of seladelpar treatment to resolve NASH and/or decrease fibrosis. In preclinical studies, Seladelpar was found to reverse NASH pathology, decrease fibrosis, inflammation, hepatic lipids and reverse insulin resistance in the *foz/foz* mouse which is a diabetic obese model of NASH. In February 2019, we announced full enrollment of 181 patients with liver biopsy proven NASH at specialized U.S. investigational centers. In June 2019, we announced results from the primary efficacy outcome, which were that treatment with seladelpar resulted in significant reductions in liver fat but that these changes were not significant when compared to placebo, which also had significant reductions. Treatment with seladelpar did, however, result in robust and clinically meaningful reductions in markers associated with liver injury. In November 2019, we terminated this trial based on initial histological observations. Although these patients had stable or improving biochemical markers of liver disease, we halted dosing of patients with seladelpar due to the lack of understanding the significance of the observations, and possible impact on patients. Subsequent investigation indicated there was no seladelpar-induced liver injury in the Phase 2b study patients. As we continue to believe seladelpar may have therapeutic benefit in NASH patients, using the data accumulated to date from our Phase 2b study, we intend to explore the potential to partner seladelpar in NASH in a combination study with other complementary agents.

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 study to evaluate the potential for MBX-2982 to stimulate the release of the hormone glucagon in response to hypoglycemia in patients with type 1 diabetes (T1D). The Phase 2a proof-of-pharmacology study will assess whether MBX-2982 can enhance glucagon secretion during insulin-induced hypoglycemia in subjects with T1D. 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. We retain full commercial rights to MBX-2982. We believe MBX-2982 may also have utility in various inflammatory diseases and are currently exploring potential opportunities to advance development.

CB-0406

In 2020 we began to evaluate CB-0406, the active metabolite of arhalofenate, a pro-drug previously studied for chronic metabolic diseases, in a single and multiple ascending dose study in healthy subjects to establish its pharmacokinetics, safety and maximum tolerated dose. Decisions on any future development are contingent on it achieving a favorable profile with respect to safety and exposure. We believe CB-0406 may have utility in various inflammatory diseases and are currently exploring potential opportunities to advance development.

COVID-19 Pandemic

In March 2020, the World Health Organization declared the global novel coronavirus disease (COVID-19) outbreak a pandemic. Accordingly, economic and health conditions in the United States and across most of the globe have changed rapidly since the end of the first quarter of 2020. As a result of the COVID-19 pandemic, we have experienced and may continue to experience disruptions that could impact aspects of our business, including our progress towards the initiation and completion of certain clinical studies, and other associated drug development activities. Possible future disruptions are currently difficult to foresee. We continue to monitor areas of potential risk which include, but are not limited to, the following:

- *Remote workforce operations*—To date, our workforce has adapted to remotely working to maintain operations. Our increased and continuing reliance on personnel working from home could potentially negatively impact future productivity, or disrupt, delay, or otherwise adversely impact our business. In addition, remote operations could increase our cyber-security risk, 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 may result in increased costs to us.
- *Clinical trial and drug manufacturing operations*—In collaboration with our clinical research organization partners, we sponsor clinical trials that take place at investigator sites in the United States and internationally. We also partner with contract manufacturing organizations to develop, manufacture, and distribute our product candidate drug supplies. To date, these collective research and development personnel and vendors have adapted to COVID-19 related travel restrictions and reduced access to work facilities through the use of remote working technologies and other measures as they continue to progress toward completion of our existing clinical trials. However, in the future, as we look to enroll and complete the clinical development of seladelpar and initiate other programs, our research and development employees and contractors may not be able to sufficiently access their applicable work facilities as a result of continued facility closure orders and the possibility that governmental authorities might further modify such restrictions. Furthermore, patients we expect to enroll in our future clinical trials may also be impacted by any ongoing travel and facility access restrictions. Although we and our contractors continue to plan for and develop pandemic-related risk mitigation strategies, it is uncertain whether these plans will continue to be sufficient to fully offset the potential impact that travel and facility access restrictions (or other unanticipated impediments) may have on our ability to execute our research and development activities in a timely and cost-effective manner. *Drug regulator interactions*—The FDA and comparable foreign regulatory agencies may experience operational interruptions or delays, which could impact timelines for regulatory meetings, submissions, trial initiations, and regulatory approvals
- *Financial reporting and compliance*—To date, there has been no adverse impact on our ability to maintain our established financial reporting functions and internal controls over financial reporting. However, our ability to prepare our financial results timely and accurately is partially dependent upon the availability of third-party information systems and other cloud-based services. Any degradation in the quality or timeliness of critical third-party information or cloud-based services could adversely impact our financial reporting capabilities.

Overall, we cannot at this time predict the specific extent, duration, or full impact that the COVID-19 outbreak will have on our consolidated financial condition and operations. The impact of the COVID-19 coronavirus outbreak on our financial performance will depend on future developments, including the duration and spread of the outbreak and related governmental advisories and restrictions, 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 Use of 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 assets and liabilities at the date of the 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 since we filed our Annual Report on Form 10-K for the year ended December 31, 2020 with the SEC on March 25, 2021. For a description of our critical accounting policies, please refer to our Annual Report on Form 10-K.

[Table of Contents](#)

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, 2021, we had an accumulated deficit of \$694.4 million, primarily as a result of expenditures for research and development and general and administrative expenses from inception to that date. All of our product candidates are at various stages of development and will require additional work and regulatory approval before they can be 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 a sufficient amount of 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 public or private equity offerings, debt financings or a combination of the foregoing.

Operating Results

Our results of operations are presented below (in thousands):

	Three Months Ended		Change Q1 2021 vs 2020
	March 31,		
	2021	2020	
<i>(\$ in thousands)</i>			
Operating expenses:			
Research and development	\$ 12,382	\$ 9,509	\$ 2,873
General and administrative	5,236	4,418	818
Total operating expenses	17,618	13,927	3,691
Loss from operations	(17,618)	(13,927)	(3,691)
Interest income	67	839	(772)
Net loss	<u><u>\$(17,551)</u></u>	<u><u>\$(13,088)</u></u>	\$ (4,463)

Research & Development Expenses

Conducting research and development is central to our business model. Research and development expenses increased \$2.9 million to \$12.4 million from \$9.5 million for the three months ended March 31, 2021 and 2020, respectively. This increase was largely due to activities associated with the development of seladelpar focusing primarily on our late-stage PBC program. In 2020, expenses included costs associated with shutdown of certain clinical trials after the seladelpar program was placed on clinical hold in late 2019 pending further investigation. This investigation was concluded in the second quarter of 2020, the clinical hold was subsequently lifted in July 2020, and we made the decision to restart the seladelpar development program. We expect that our research and development expenses will continue to increase in the future due to our decision to reinstate development of seladelpar.

Table of Contents

For the three months ended March 31, 2021 and 2020, research and development expenses were \$12.4 million and \$9.5 million, respectively. Research and development expenses are detailed in the table below (in thousands):

	Three Months Ended March 31,		Change Q1
	2021	2020	2021 vs 2020
Project costs:			
Seladelpar PBC clinical studies	\$ 5,903	\$5,584	\$ 319
Seladelpar NASH clinical studies	(10)	897	(907)
Seladelpar PSC clinical studies	—	252	(252)
Seladelpar drug manufacturing & development	754	237	517
Seladelpar other studies	123	125	(2)
Non-seladelpar studies	982	230	752
Total project costs	7,752	7,325	427
Internal research and development costs	4,630	2,184	2,446
Total research and development	<u>\$12,382</u>	<u>\$9,509</u>	\$ 2,873

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 and manufacturing clinical trial and other materials; 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 three months ended March 31, 2021 and 2020

Total project costs increased by \$0.4 million to \$7.8 million from \$7.3 million for the three months ended March 31, 2021 and 2020, respectively. Project costs for the three months ended March 31, 2021 and 2020 primarily consisted of seladelpar-related clinical trial expenses for PBC. These cost increases were primarily driven by the decision to restart development of the seladelpar program in July 2020 following the FDA's decision to lift the clinical hold on the program. Internal research and development costs increased by \$2.4 million to \$4.6 million from \$2.2 million for the three months ended March 31, 2021 and 2020, respectively, primarily due to higher employee compensation incurred in the first three months of 2021 as compared to the first quarter of 2020 as we hired additional research and development personnel to support the restart of our clinical studies. As we continue to progress late-stage development of seladelpar in PBC as well as development activities associated with other product candidates, we expect both total project and internal costs 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 three months ended March 31, 2021 and 2020

General and administrative expenses increased by \$0.8 million to \$5.2 million from \$4.4 million for the three months ended March 31, 2021 and 2020, respectively. The increase was driven primarily by the hiring of additional general and administrative personnel in the second half of 2020 after we made the decision to restart our development activities. We expect general and administrative expenses to increase in the future as we continue to add administrative personnel and expand our infrastructure in support of our drug development activities.

Interest Income

Interest income decreased by \$0.8 million to \$0.1 million from \$0.8 million for the three months ended March 31, 2021 and 2020, respectively. The decrease in interest income was driven primarily by lower prevailing interest rates and a reduced investment portfolio balance compared to the prior year period.

[Table of Contents](#)

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, 2021, cash, cash equivalents and marketable securities totaled \$125.5 million, compared to \$146.3 million at December 31, 2020. Our cash, cash equivalents and investments are held in a variety of interest-bearing instruments, including deposits, money market funds, corporate debt, commercial paper, asset-backed securities, U.S. treasury securities, and supranational debt securities investments. We invest cash in excess of immediate requirements with a view toward liquidity and capital preservation, and we seek to minimize the potential effects of concentration and degrees of risk. We believe these funds are sufficient to fund our current operating plan into mid-2022.

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,	
	2021	2020
Net cash used in operating activities	\$(20,561)	\$(14,708)
Net cash provided by investing activities	35,694	46,633
Net increase in cash and cash equivalents	<u>\$ 15,133</u>	<u>\$ 31,925</u>

Operating Activities: Net cash used in operating activities for the three months ended March 31, 2021 increased by \$5.9 million to \$20.6 million as compared to \$14.7 million for the same period in the prior year, primarily due to an increase in our net loss to \$17.6 million from \$13.1 million in the prior year period as a result of our restart of the seladelpar development program following the lifting of the clinical hold in July 2020. In addition, cash was used to fund changes in our working capital.

Investing Activities: Net cash provided by investing activities was \$35.7 million for the three months ended March 31, 2021 compared to \$46.6 million for the same period in the prior year, primarily due to the timing of our investments in marketable securities and portfolio risk management.

Off-Balance Sheet Arrangements

We do not currently have, nor have we ever had, any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts.

[Table of Contents](#)

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation as of March 31, 2021 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, 2021.

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, 2021, 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 remotely 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 seeks damages in an unspecified amount as well as injunctive relief. We have stated in pleadings that we did not request or take any steps to obtain Genfit’s protocol synopsis, have taken diligent steps to remove and quarantine it, and are not using any Genfit trade secrets in our clinical trials. 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 have not yet filed our Reply to the Amended Complaint. We intend to defend ourselves vigorously.

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 of 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 the COVID-19 Pandemic

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

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 activities commensurate with the magnitude of the shortfall or our product development activities may cease altogether.
- 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 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 product candidates, we may be unable to generate any revenue.
- The commercial success of our products is subject to significant competition from products or product candidates that may be superior to, or more cost effective than, our products or product candidates.

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.
- Our stock price is extremely volatile.

Risks Related to the COVID-19 Pandemic

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

On January 30, 2020, the World Health Organization declared the outbreak of the coronavirus causing the disease COVID-19 a “Public Health Emergency of International Concern,” and on March 11, 2020, the World Health Organization characterized the outbreak as a “pandemic.” While the COVID-19 pandemic did not materially adversely affect our business operations in the three month periods ended March 31, 2021 and 2020, economic and health conditions in the United States and across most of the globe have continued to change during the first quarter of 2021. As a result of the COVID-19 pandemic, 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 associated drug development activities. Possible future disruptions are currently difficult to foresee and include, but are not limited to, potential risk areas as noted below:

Table of Contents

- We are currently starting up clinical trials in geographies that are affected by the COVID-19 pandemic. While we have not experienced significant impacts to our clinical activities through March 31, 2021, we believe that the COVID-19 pandemic could potentially have an impact on various aspects of our clinical activities in the future. For example, pandemic related restrictions, including stay-at-home orders and curtailment of all but essential services, could reduce the rate of patient enrollment in our RESPONSE clinical trial and other clinical studies, 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 unable to efficiently collaborate to conduct investigator site activities in-person at the sites (as per standard practice) and may be required to delay, or alter their approach to complete this work due to diversion of resources at clinical sites or continued government-imposed limitations on travel. Further, our employees and representatives from our contract manufacturing organizations may experience unanticipated challenges producing and distributing sufficient quantities of clinical drug supplies for use in our clinical trials.
- We have limited access to our corporate office and requested that most of our personnel, including all of our administrative employees, work remotely, and restricted on-site staff to only those personnel and contractors who must perform essential activities that must be completed on-site. The COVID-19 pandemic could disrupt our ability to secure supplies for our operations. The safety, health and well-being of our workforce is of primary concern and we may need to enact further precautionary measures to help minimize the risk of our employees being exposed to the novel coronavirus.
- Our increased and 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.
- Our employees and contractors involved in conducting our research and development activities may not be able to access their applicable work facilities for an extended period of time as a result of facility closure orders and the possibility that governmental authorities further modify such access restrictions.
- 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 COVID-19 pandemic continues to evolve. The extent to which the pandemic 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, variants to COVID-19 that continue to arise, the duration of the pandemic, travel restrictions and actions to contain the pandemic or treat its impact, such as social distancing and quarantines or lock-downs in the United States, particularly in the San Francisco Bay Area where our executive offices are located, and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

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, 2021, we had cash, cash equivalents and marketable securities of approximately \$125.5 million. We may need to raise additional equity and/or debt capital to fund our continued operations, including clinical trials and other product development. We may also choose to raise additional equity and/or debt capital if appropriate opportunities become available. 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 in financing our product development activities or do not have appropriate developmental assets, we will curtail our product development activities commensurate with the magnitude of the shortfall or our product development activities may cease altogether. To the extent that any costs of the 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 affect any of such transactions on acceptable terms, if at all.

Table of Contents

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 filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; 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 will have a material adverse effect on our business, operating results, prospects, and on our ability to develop our product candidates.

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. Our ability to generate revenues from product sales depends heavily on our success in generating a pipeline of product candidates.

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 product candidates, 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.

[Table of Contents](#)

If we raise additional funds through collaborations, strategic alliances, or 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.

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, enrollment of sufficient subjects willing to obtain a liver biopsy;
- 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 conduct 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;

Table of Contents

- the number of patients in our RESPONSE clinical trial that choose to have biopsies may be insufficient to satisfy regulatory requirements;
- clinical investigators or study subjects fail to comply with clinical study protocols;
- trial conduct and data analysis errors may occur, including, but not limited to, data entry and/or labeling 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;
- 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.

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.

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

- inability to raise funding necessary to initiate or continue a trial;
- 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 the need to enroll additional subjects willing to have biopsies in the RESPONSE trial;
- 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;

[Table of Contents](#)

- 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 and impair our ability to generate regulatory and commercialization milestones and royalties, all of which could 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. In November and December 2019, due to histologic observations in our NASH clinical trial, all seladelpar clinical trials were terminated, pending further analysis of data from the NASH trial and further discussions with the FDA. Although in June 2020 we shared data and conclusions from an expert panel with the FDA, and in July 2020 the FDA lifted the clinical hold on our seladelpar program, this process substantially delayed the development of seladelpar. 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.

[Table of Contents](#)

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;
- the FDA or foreign regulatory authority might not approve our third party manufacturers' processes or facilities for clinical or commercial product;
- the FDA or foreign regulatory authority may change its approval policies or adopt new regulations;
- the FDA or foreign regulatory authority may disagree with the design or implementation of our clinical studies;
- the FDA or foreign regulatory authority may not accept clinical data from studies that are conducted in countries where the standard of care is potentially different from that in the United States;
- the results of clinical studies may not meet the level of statistical significance required by the FDA or foreign 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 product candidates or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. Our product candidates 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

[Table of Contents](#)

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 product candidates 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 current or any future product candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any product candidates that we commercialize, if approved, 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 product candidates 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 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 for which we obtain marketing approval. Restrictions under applicable federal and state health care laws and regulations, include the federal Anti-Kickback Statute, the federal False Claims Act, the 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 recent efforts by the Trump administration to repeal or replace certain aspects of the PPACA. For example, President Trump signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. 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. The United States Supreme Court is currently reviewing the constitutionality of the PPACA, but it is unclear when a decision will be made. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the PPACA and our business. Further, other legislative changes have been adopted since the PPACA was enacted, such as the Budget Control Act of 2011 and the American Taxpayer Relief Act of 2012, which have resulted in reduced reimbursement under the Medicare program.

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

[Table of Contents](#)

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 pandemic.

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 product candidates.

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 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 product. 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 may 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.

[Table of Contents](#)

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 to scale-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 product candidates 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;

Table of Contents

- 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 any product candidates. 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 for Harmonization 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 candidate 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

Table of Contents

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 product candidates 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 product candidates;
- 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 product candidates 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 candidate;
- acceptance of the product by physicians, other health care providers and patients as a safe and effective treatment;
- the potential and perceived advantages of product candidates 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 any product candidate that we successfully develop does not achieve broad market acceptance among physicians, patients, health care payors and the medical community, the revenues that it generates from its sales will be limited.

Even if our product candidates receive regulatory approval, the products may not gain market acceptance among physicians, patients, health care payors and the medical community. Coverage and reimbursement of our product candidates by third-party payors, including government payors, generally is also necessary for commercial success. The degree of market acceptance of any of our approved products will depend upon a number of factors, including:

- the efficacy and safety, as demonstrated in clinical studies;
- the risk/benefit profile of our product candidates;
- the prevalence and severity of any side effects;
- the clinical indications for which the product is approved;
- acceptance of the product by physicians, other health care providers and patients as a safe and effective treatment;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in a broader patient group, including if physicians prescribe our products for uses outside the approved indications;
- the cost of treatment in relation to alternative treatments;
- the timing of market introduction of competitive products;
- the availability of coverage and adequate reimbursement by third party payors and government authorities;
- relative convenience and ease of administration; and
- the effectiveness of our or our partners' sales, marketing and distribution efforts.

[Table of Contents](#)

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, health care payors and patients, we may not generate sufficient revenue from these products 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 candidates, 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 product candidates.

If we are unable to build our own sales force or negotiate a strategic partnership for the commercialization of our product candidates, 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.

[Table of Contents](#)

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 candidate 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 patient self-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 will 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

[Table of Contents](#)

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 seladelpar, and our other 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 product candidates;
- 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 product candidates; 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 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 product candidates in development. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing based on 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 and product candidates. 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 provoked 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 proprietary know-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 and our collaborators 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 candidate 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 are currently engaged in legal proceedings with Genfit S.A. (Genfit), which alleges that we misappropriated some of their 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

[Table of Contents](#)

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 expect to 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 any non-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 not valid 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 if 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 this type of 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, on April 27, 2020, a stockholder filed a preliminary proxy statement containing proposed opposition to our preliminarily filed proxy statement on April 27, 2020, 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 highly 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 and technical 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 the loss of services of any executive or key employee, 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.

[Table of Contents](#)

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 development programs as a result of the FDA's lift of the clinical hold on the seladelpar development programs, we are expanding our employee base to increase our managerial, clinical, scientific, 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 consolidated 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 the ongoing COVID-19 pandemic and remote work requirements. 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 introduces 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 has historically been listed on the Nasdaq Capital Market under the symbol "CBAY" and in the second quarter of 2018 it began trading on the Nasdaq Global Select Market. Historically, trading volume for our common stock has been limited. 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 generally will continue to support an active public trading market for our common stock or how liquid will be that public market.

[Table of Contents](#)

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:

- adverse or inconclusive results or delays in preclinical testing or clinical trials;
- 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 maintain our existing collaborations or enter into new collaborations;
- failure by us or our licensors and collaboration partners 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 future 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, our collaboration partners 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.

[Table of Contents](#)

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, our management is 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, 2021 was 2,434,439 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 amended and restated 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.

[Table of Contents](#)

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.

Table of Contents

Item 6.	Exhibits
<u>Exhibit Number</u>	<u>Description of Document</u>
3.1	<u>Amended and Restated Certificate of Incorporation (Filed with the SEC as Exhibit 3.1 to our Amendment No. 2 to Registration Statement on Form 10, filed with the SEC on October 17, 2013, SEC File No. 000-55021).</u>
3.2	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation (Filed with the SEC as Exhibit 3.1 to our Current Report on Form 8-K, filed with the SEC on June 26, 2020, SEC File No.001-36500).</u>
3.3	<u>Amended and Restated By-Laws. (Filed with the SEC as Exhibit 3.2 to our Amendment No. 2 to Registration Statement on Form 10, filed with the SEC on October 17, 2013, SEC File No. 000-55021).</u>
4.1	Reference is made to Exhibits <u>3.1</u> , <u>3.2</u> and <u>3.3</u> .
31.1	<u>Certification of President and Chief Executive Officer (Principal Executive Officer) pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Exchange Act.</u>
31.2	<u>Certification of Vice President, Finance (Principal Financial and Accounting Officer) pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Exchange Act.</u>
32.1	<u>Certification of President and Chief Executive Officer (Principal Executive Officer) and Vice President, Finance (Principal Financial and Accounting Officer) pursuant to 13a-14(b) or 15d-14(b) of the Exchange Act.</u>
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL, tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Schema Linkbase Document
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Labels Linkbase Document
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in exhibit 101)

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 13, 2021

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

Date: May 13, 2021

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 Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date May 13, 2021

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

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 Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; 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 13, 2021

/s/ Daniel Menold

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

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, 2021, 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 13, 2021.

/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.