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 September 30, 2019

OR

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

FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission File Number 001-36500

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

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

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

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, $0.0001 par value per share	CBAY	Nasdaq Global Select Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

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

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

As of October 31, 2019, there were 68,701,043 shares of the registrant's Common Stock outstanding.

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

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 43,462	$ 48,995
Marketable securities	175,132	129,669
Accrued interest receivable	509	304
Prepaid research and development expenses	7,900	1,670
Other prepaid expenses	768	924
Total current assets	227,771	181,562
Property and equipment, net	2,549	2,905
Operating lease right-of-use asset	219	-
Other assets	1,261	2,280
Total assets	$ 231,800	$ 186,747
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,494	$ 1,973
Accrued research and development expenses	10,819	8,588
Other accrued liabilities	5,045	3,854
Total current liabilities	17,358	14,415
Long-term portion of operating lease liability	1,851	-
Other liabilities	-	1,914
Total liabilities	19,209	16,329
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: 100,000,000 shares authorized; 68,701,043 and 59,456,493 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	7	6
Additional paid-in capital	808,866	693,534
Accumulated other comprehensive income (loss)	177	(58)
Accumulated deficit	(596,459)	(523,064)
Total stockholders' equity	212,591	170,418
Total liabilities and stockholders' equity	$ 231,800	$ 186,747

See accompanying notes to the condensed consolidatedfinancial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 23,193	$ 17,853	$ 62,900	$ 41,727
General and administrative	4,514	3,276	14,706	10,223
Total operating expenses	27,707	21,129	77,606	51,950
Loss from operations	(27,707)	(21,129)	(77,606)	(51,950)
Other income (expense):				
Interest income	1,425	1,113	4,211	2,882
Interest expense	-	-	-	(336)
Loss on extinguishment of debt	-	-	-	(407)
Other income (expense), net	-	1,453	-	(3,288)
Total other income (expense)	1,425	2,566	4,211	(1,149)
Net loss	$ (26,282)	$ (18,563)	$ (73,395)	$ (53,099)
Other comprehensive (loss) income:				
Unrealized (loss) gain on marketable securities	(51)	36	235	13
Total other comprehensive (loss) income	(51)	36	235	13
Comprehensive loss	$ (26,333)	$ (18,527)	$ (73,160)	$ (53,086)
Basic net loss per common share	$ (0.38)	$ (0.31)	$ (1.10)	$ (0.93)
Diluted net loss per common share	$ (0.38)	$ (0.34)	$ (1.10)	$ (0.93)
Weighted average common shares outstanding used to calculate basic net loss per common share	68,701,043	59,121,600	66,454,750	57,255,666
Weighted average common shares outstanding used to calculate diluted net loss per common share	68,701,043	59,387,780	66,454,750	57,298,105

See accompanying notes to the condensed consolidatedfinancial statements.

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

	Nine Months Ended September 30,	
	2019	**2018**
Operating activities		
Net loss	$ (73,395)	$ (53,099)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	422	39
Stock-based compensation expense	7,483	5,275
Net accretion and amortization of investments in marketable securities	(1,909)	(1,358)
Non-cash interest associated with debt discount accretion	-	148
Loss on extinguishment of debt	-	407
Change in fair value of warrant liability	-	3,710
Gain on extinguishment of warrant liability	-	(422)
Accretion of tenant improvement allowance	-	(154)
Changes in assets and liabilities:		
Receivable from collaboration	-	5,000
Interest receivable and other current assets	(205)	(93)
Prepaid expenses	(6,074)	(585)
Other assets	1,019	(729)
Accounts payable	(479)	318
Accrued liabilities	3,363	6,245
Accrued interest payable	-	(43)
Net cash used in operating activities	(69,775)	(35,341)
Investing activities		
Purchases of property and equipment	(289)	(60)
Purchases of marketable securities	(246,180)	(249,422)
Proceeds from maturities of marketable securities	198,881	168,600
Proceeds from sale of marketable securities	3,980	-
Net cash used in investing activities	(43,608)	(80,882)
Financing activities		
Proceeds from issuance of common stock, net of issuance costs	107,746	135,520
Proceeds from issuance of common stock pursuant to equity award plans	104	3,547
Proceeds from issuance of common stock upon exercise of warrants	-	2,550
Repayment of facility loan principal	-	(6,527)
Payment of fees to extinguish facility loan	-	(126)
Net cash provided by financing activities	107,850	134,964
Net (decrease) increase in cash and cash equivalents	(5,533)	18,741
Cash and cash equivalents at beginning of period	48,995	23,054
Cash and cash equivalents at end of period	$ 43,462	$ 41,795
Supplemental disclosure		
Cash paid for amounts included in the measurement of lease liabilities	$ 470	$ -
Cash paid for interest	$ -	$ 231
Supplemental non-cash investing and financing activities		
Lessor funded lease incentives included in other current assets	$ -	$ 2,100
Issuance of common stock upon warrant exercises	$ -	$ 9,379

See accompanying notes to the condensed consolidatedfinancial statements.

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

	Three and Nine Months Ended September 30, 2019					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances as of December 31, 2018	59,456,493	$ 6	$ 693,534	$ (58)	$ (523,064)	$ 170,418
Issuance of common stock upon exercise of stock options and incentive awards	37,550	-	97	-	-	97
Stock-based compensation expense	-	-	2,342	-	-	2,342
Issuance of common stock, net of $7,254 issuance costs	9,200,000	1	107,745	-	-	107,746
Net loss	-	-	-	-	(23,075)	(23,075)
Net unrealized gain on marketable securities	-	-	-	103	-	103
Balances as of March 31, 2019	68,694,043	$ 7	$ 803,718	$ 45	$ (546,139)	$ 257,631
Issuance of common stock upon exercise of stock options and incentive awards	7,000	-	7	-	-	7
Stock-based compensation expense	-	-	2,276	-	-	2,276
Net loss	-	-	-	-	(24,038)	(24,038)
Net unrealized gain on marketable securities	-	-	-	183	-	183
Balances as of June 30, 2019	68,701,043	$ 7	$ 806,001	$ 228	$ (570,177)	$ 236,059
Stock-based compensation expense	-	-	2,865	-	-	2,865
Net loss	-	-	-	-	(26,282)	(26,282)
Net unrealized loss on marketable securities	-	-	-	(51)	-	(51)
Balances as of September 30, 2019	68,701,043	$ 7	$ 808,866	$ 177	$ (596,459)	$ 212,591

See accompanying notes to the condensed consolidatedfinancial statements.

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

	Three and Nine Months Ended September 30, 2018					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances as of December 31, 2017	44,408,796	$ 4	$ 535,503	$ (44)	$ (450,516)	$ 84,947
Issuance of common stock upon exercise of warrants	297,144	-	3,753	-	-	3,753
Issuance of common stock upon exercise of stock options and incentive awards	667,656	-	3,276	-	-	3,276
Stock-based compensation expense	-	-	1,796	-	-	1,796
Issuance of common stock, net of $8,553 issuance costs	13,340,000	2	135,518	-	-	135,520
Net loss	-	-	-	-	(17,005)	(17,005)
Net unrealized loss on marketable securities	-	-	-	(88)	-	(88)
Balances as of March 31, 2018	58,713,596	$ 6	$ 679,846	$ (132)	$ (467,521)	$ 212,199
Issuance of common stock upon exercise of warrants	185,507	-	2,484	-	-	2,484
Issuance of common stock upon exercise of stock options and incentive awards	60,833	-	245	-	-	245
Stock-based compensation expense	-	-	1,751	-	-	1,751
Net loss	-	-	-	-	(17,531)	(17,531)
Net unrealized gain on marketable securities	-	-	-	65	-	65
Balances as of June 30, 2018	58,959,936	$ 6	$ 684,326	$ (67)	$ (485,052)	$ 199,213
Issuance of common stock upon exercise of warrants	474,194	-	5,691	-	-	5,691
Issuance of common stock upon exercise of stock options and incentive awards	5,000	-	26	-	-	26
Stock-based compensation expense	-	-	1,728	-	-	1,728
Net loss	-	-	-	-	(18,563)	(18,563)
Net unrealized gain on marketable securities	-	-	-	36	-	36
Balances as of September 30, 2018	59,439,130	$ 6	$ 691,771	$ (31)	$ (503,615)	$ 188,131

See accompanying notes to the condensed consolidatedfinancial statements.

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 (MBX-8025). Seladelpar is currently being developed or evaluated for the treatment of the liver diseases primary biliary cholangitis (PBC), primary sclerosing cholangitis (PSC), 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 nine months ended September 30, 2019, the Company incurred a net loss of $73.4 million and used $69.8 million of cash in operations. At September 30, 2019, the Company had an accumulated deficit of $596.5 million. CymaBay expects to incur substantial research and development expenses as it continues to study 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. As a result, management expects operating losses to continue in future years. The Company's ability to achieve profitability is dependent primarily on its ability to successfully develop, acquire or in-license additional product candidates, continue clinical trials for product candidates currently in clinical development, obtain regulatory approvals, and support commercialization activities for its product candidates. Products developed by the Company 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 September 30, 2019, the Company had cash, cash equivalents and marketable securities totaling $218.6 million, which the Company believes is sufficient to fund its current operating plan into 2021. The Company expects to incur substantial expenditures in the future for the development and potential commercialization of its product candidates. Because of this, the Company expects its future liquidity and capital resource needs will be impacted by numerous factors, including but not limited to, costs for the Company's Phase 2 clinical trial in PSC, the ongoing Phase 2b clinical trial activities in NASH, and most significantly, the timing and conduct of PBC development activities. The Company's PBC development activities include two Phase 3 clinical trials, one of which is a long-term open label study, as well as other new drug application (NDA)-enabling studies. The Company has obtained and expects to obtain additional funding to develop its products and fund future operating losses, as appropriate, through equity offerings; debt financing; one or more possible licenses, collaborations or other similar arrangements with respect to development and/or commercialization rights of its 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 its business, results of operations, and financial condition.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying interim condensed consolidated financial statements are unaudited and are comprised 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) and following 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 GAAP can be condensed or omitted. Certain reclassifications have been made to the prior period amounts to conform to the current year presentation. "Prepaid research and development expenses" and "Other prepaid expenses", which were previously reported together as "Prepaid expenses" on the condensed balance sheet, are now reported as separate line items.

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 GAAP and should be read in conjunction with the Company's financial statements and accompanying notes for the fiscal year ended December 31, 2018, which is contained in the Company's Annual Report on Form 10-K as filed with the SEC on February 28, 2019. The results for the three and nine months ended September 30, 2019 are not necessarily indicative of results to be expected for the entire year ending December 31, 2019 or future operating periods.

Use of Estimates

The condensed consolidated financial statements have been prepared in accordance with 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. The Company believes significant judgment can be involved in estimating stock-based compensation, accrued research and development expense, and the fair value of the Company's common stock warrants. 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 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 expenses, other 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, accrued interest receivable, prepaid expenses, other 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.

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 September 30, 2019			
	Level 1	Level 2	Level 3	Total Fair Value
Cash equivalents:				
Money market funds	$ 38,715	$ -	$ -	$ 38,715
Total cash equivalents	38,715	-	-	38,715
Marketable securities:				
U.S. and foreign commercial paper	-	49,044	-	49,044
U.S. and foreign corporate debt securities	-	58,877	-	58,877
Asset-backed securities	-	38,746	-	38,746
U.S. treasury securities	-	28,465	-	28,465
Total marketable securities	-	175,132	-	175,132
Total assets measured at fair value	$ 38,715	$ 175,132	$ -	$ 213,847

	As of December 31, 2018			
	Level 1	Level 2	Level 3	Total Fair Value
Cash equivalents:				
Money market funds	$ 39,481	$ -	$ -	$ 39,481
U.S. and foreign commercial paper	-	6,469	-	6,469
Total cash equivalents	39,481	6,469	-	45,950
Marketable securities:				
U.S. and foreign commercial paper	-	51,627	-	51,627
U.S. and foreign corporate debt securities	-	34,634	-	34,634
Asset-backed securities	-	25,472	-	25,472
U.S. treasury securities	-	17,936	-	17,936
Total marketable securities	-	129,669	-	129,669
Total assets measured at fair value	$ 39,481	$ 136,138	$ -	$ 175,619

The Company estimates the fair value of its corporate debt, commercial paper, asset backed securities, and U.S. treasury 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.

There were no transfers between Level 1 and Level 2 during the periods presented.

Historically, the Company held a Level 3 liability associated with common stock warrants that were issued in connection with the Company's financings completed in September and October 2013, January 2014, and August 2015. The warrants were accounted for as liabilities until either they were exercised or expired in September 2018.

The following table sets forth a summary of the changes in the fair value of the Company's liabilities measured using Level 3 inputs (in thousands):

	For the Nine Months Ended September 30,	
	2019	2018
Balance, beginning of period	$ -	$ 6,091
Change in fair value	-	3,710
Settlement of financial instruments	-	(9,379)
Extinguishment of financial instruments	-	(422)
Balance, end of period	$ -	$ -

Cash, Cash Equivalents and Marketable Securities

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

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, and U.S. treasury 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.

The following tables summarize amortized cost, unrealized gain and loss, and fair value of the Company's available for sale marketable securities (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Fair Value
As of September 30, 2019:				
U.S. and foreign commercial paper	$ 49,044	$ -	$ -	$ 49,044
U.S. and foreign corporate debt securities	58,774	103	-	58,877
Asset-backed securities	38,695	51	-	38,746
U.S. treasury securities	28,442	23	-	28,465
Total marketable securities	$ 174,955	$ 177	$ -	$ 175,132

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Fair Value
As of December 31, 2018:				
U.S. and foreign commercial paper	$ 51,627	$ -	$ -	$ 51,627
U.S. and foreign corporate debt securities	34,668	-	(34)	34,634
Asset-backed securities	25,494	-	(22)	25,472
U.S. treasury securities	17,938	-	(2)	17,936
Total marketable securities	$ 129,727	$ -	$ (58)	$ 129,669

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 in 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.

Leases

The Company has one lease, a non-cancelable operating lease agreement for its corporate offices. Prior to January 1, 2019, the Company recognized related rent expense on a straight-line basis over the term of the lease. Incentives granted under the Company's facilities lease, including allowances for leasehold improvements and rent holidays, were recognized as reductions to rental expense on a straight-line basis over the term of the lease. Deferred rent consisted of the difference between cash payments and the rent expense recognized.

Subsequent to the adoption of the new leasing standard on January 1, 2019, the Company recognizes a lease asset for its right to use the underlying asset and a lease liability for the corresponding lease obligation. The Company determines whether an arrangement is or contains a lease at contract inception. Operating leases are included in operating lease right-of-use assets, other accrued liabilities, and long-term portion of operating lease liabilities in our condensed consolidated balance sheet at September 30, 2019. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the net present value of lease payments, the Company uses its incremental borrowing rate based on the information available at the lease commencement date. The incremental borrowing rate represents the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of a lease. The Company considers a lease term to be the noncancelable period that it has the right to use the underlying asset, including any periods where it is reasonably assured the Company will exercise the option to extend the contract. Periods covered by an option to extend are included in the lease term if the lessor controls the exercise of that option.

The operating lease right-of-use assets also include any lease payments made and exclude lease incentives. Lease expense is recognized on a straight-line basis over the expected lease term. The Company has elected to not separate lease and non-lease components for its leased assets and accounts for all lease and non-lease components of its agreements as a single lease component.

Common Stock Warrant Liability

Historically, the Company's outstanding common stock warrants issued in connection with certain equity and debt financings that occurred in 2013 through 2015 were classified as liabilities in the accompanying condensed consolidated balance sheets because of certain contractual terms that preclude equity classification. As of September 30, 2018, all outstanding warrants related to these financings had been exercised or had expired. Upon expiration, the remaining fair value of the liability was extinguished and credited to other income (expense), net in the Company's condensed consolidated statement of operations. Prior to expiration, the Company estimated the fair value of common stock warrants at each reporting period until the exercise of the warrants, at which time the liability was revalued and reclassified to stockholders' equity. The determination of fair value of these common stock warrants required management to make certain assumptions regarding subjective input variables such as timing, probability and valuation impact of certain potential strategic events, expected term, dividends, expected volatility and risk-free interest rates.

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.

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 of the expense. 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

Employee and director 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 and on an accelerated basis for stock options with performance conditions. For stock options with performance conditions, the Company evaluates the probability of achieving performance conditions at each reporting date. The Company begins to recognize the expense when it is deemed probable that the performance conditions will be met. 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. The Company is also required to make estimates as to the probability of achieving the specific performance criteria. 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.

Equity awards granted to non-employees are valued using the Black-Scholes option pricing model. Stock-based compensation expense for nonemployee services has historically been subject to remeasurement at each reporting date as the underlying equity instruments vest and was recognized as an expense over the period during which services are received. Upon the adoption of ASU 2018-07, *Compensation – Stock Compensation* on January 1, 2019, the valuation was fixed at the implementation date and will be recognized as an expense on a straight-line basis over the remaining service period.

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 and common stock warrants, if dilutive.

The calculation of diluted loss per share also requires that, to the extent the average market price of the underlying shares for the reporting period exceeds the exercise price of the common stock warrants and the presumed and actual exercise or expiration of such securities are dilutive to earnings (net loss) per share for the period, adjustments to net income or net loss used in the calculation are required to remove the change in fair value of the common stock warrant liability for the period. Likewise, adjustments to the denominator are required to reflect the related dilutive shares.

In all periods presented, the Company's outstanding stock options were excluded from the calculation of diluted net loss per share because their effects were 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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Numerator:				
Net loss allocated to common stock-basic	$ (26,282)	$ (18,563)	$ (73,395)	$ (53,099)
Adjustments for revaluation and extinguishment of common stock warrants	-	(1,462)	-	(422)
Net loss allocated to common stock-diluted	$ (26,282)	$ (20,025)	$ (73,395)	$ (53,521)
Denominator:				
Weighted average number of common stock shares outstanding - basic	68,701,043	59,121,600	66,454,750	57,255,666
Dilutive securities:				
Common stock warrants	-	266,180	-	42,439
Weighted average number of common stock shares outstanding - diluted	68,701,043	59,387,780	66,454,750	57,298,105
Net loss per share - basic:	$ (0.38)	$ (0.31)	$ (1.10)	$ (0.93)
Net loss per share - diluted:	$ (0.38)	$ (0.34)	$ (1.10)	$ (0.93)

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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Common stock options	7,949	5,570	7,949	5,570
Incentive awards	127	130	127	130
	8,076	5,700	8,076	5,700

Recently Adopted Accounting Pronouncements

Accounting Standards Update 2016-02 and 2018-11

In February 2016, the FASB issued ASU No. 2016-02,*Leases (Topic 842).* The new standard requires the recognition of lease liabilities and right-of-use (ROU) assets on the balance sheet arising from lease transactions at the lease commencement date and the disclosure of key information about leasing arrangements. In July 2018, the FASB issued ASU 2018-11, Leases (Topic 842) Targeted Improvements, which provides an additional transition method in which the new lease standard is applied at the adoption date and recognized as a cumulative-effect adjustment to retained earnings without adjustment to comparative periods. The amendment has the same effective date and transition requirements as the new lease standard.

The Company adopted this standard on January 1, 2019 using the modified retrospective approach and elected the package of practical expedients permitted under transition guidance, which allowed the Company to carry forward its historical assessments of: 1) whether contracts are or contain leases, 2) lease classification and 3) initial direct costs. The Company did not elect the practical expedient allowing the use-of-hindsight which would require the Company to reassess the lease term of its leases based on all facts and circumstances through the effective date and did not elect the practical expedient pertaining to land easements as this is not applicable to the current contract portfolio. The Company elected the post-transition practical expedient to not separate lease components from nonlease components for all existing lease classes. The Company also elected a policy of not recording leases on its condensed consolidated balance sheets when the leases have a term of 12 months or less and the Company is not reasonably certain to elect an option to purchase the leased asset.

The adoption of this standard resulted in the recognition of a ROU asset and lease liabilities of $0.2 million and $2.5 million, respectively, and the derecognition of the deferred rent balance of $2.3 million as of January 1, 2019. The adoption of the standard had no impact on the Company's condensed consolidated statements of operations and comprehensive loss or to its cash flows from or used in operating, financing, or investing activities on its condensed consolidated statements of cash flows. No cumulative-effect adjustment within accumulated deficit was required to be recorded as a result of adopting this standard.

Accounting Standards Update 2018-08

On January 1, 2019 the Company adopted ASU No. 2018-08, Not-For-Profit Entities (Topic 958):*Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made* (ASU No. 2018-08), which is intended to clarify and improve the scope and the accounting guidance for contributions received and contributions made. The amendments in ASU No. 2018-08 assist entities in (1) evaluating whether transactions should be accounted for as contributions (nonreciprocal transaction) within the scope of Topic 958, Not-for-Profit Entities, or as exchange (reciprocal) transactions subject to other guidance and (2) determining whether a contribution is conditional. This amendment applies to all entities that make or receive grants or contributions. The adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.

Accounting Standards Update 2018-07

On January 1, 2019, the Company adopted ASU 2018-07,*Compensation – Stock Compensation* (Topic 718). This update simplifies the accounting for share-based payments to non-employees by aligning it with the accounting guidance for share-based payments for employees. The ASU expands the scope of Topic 718, Compensation – Stock Compensation, which currently only includes share-based payments issued to employees, to also include share-based payments issued to non-employees for goods and services. Consequently, the accounting for share-based payments to non-employees and employees is substantially aligned. The adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.

SEC Securities Act Release No. 33-10532

In August 2018, the SEC adopted amendments to certain disclosure requirements in Securities Act Release No. 33-10532,*Disclosure Update and Simplification.* The amendments became effective on November 5, 2018 and impact the Company's condensed consolidated financial statements through, among other things, the addition of a requirement to present a statement of stockholders' equity for interim periods. As a result of adopting this guidance, the Company is presenting its interim statement of stockholders' equity in this Form 10-Q for the quarter and year to date period ending September 30, 2019. Additionally, the guidance also simplified certain non-material disclosures in its SEC filings.

Recently Issued Accounting Pronouncements

Accounting Standards Update 2018-18

In November 2018, the FASB issued ASU 2018-18, Collaborative Arrangements (Topic 808):*Clarifying the Interaction between Topic 808 and Topic 606*. The guidance clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer. For the company, the amendment will be effective January 1, 2020. The Company is evaluating the impact this guidance will have on its consolidated financial statements and related disclosures.

Accounting Standards Update 2018-15

In August 2018, the FASB issued ASU No. 2018-15, Intangibles (Topic 350):*Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. This new standard also requires customers to expense the capitalized implementation costs of a hosting arrangement that is a service contract over the term of the hosting arrangement. This ASU is effective for public companies for fiscal years beginning after December 15, 2019. This new standard can be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company is currently evaluating the impact of adoption of this ASU on its consolidated financial statements.

Accounting Standards Update 2018-13

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820):*Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement* which modifies the disclosure requirements in Topic 820, Fair Value Measurement, by removing certain disclosure requirements related to the fair value hierarchy, modifying existing disclosure requirements related to measurement uncertainty and adding new disclosure requirements, such as disclosing the changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period and disclosing the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. This ASU is effective for public companies for fiscal years beginning after December 15, 2019, including interim periods within that fiscal year. Early adoption is permitted for any removed or modified disclosures. The Company is currently evaluating the impact of adoption of this ASU on its condensed consolidated financial statements.

Accounting Standards Update 2016-13

In June 2016, the FASB issued ASU No. 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. The guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted for annual periods after December 15, 2018. The Company is currently evaluating the impact of adoption of this ASU on its condensed consolidated financial statements.

3. Other Accrued Liabilities

Other accrued liabilities consist of (in thousands):

	September 30, 2019	December 31, 2018
Accrued compensation	$ 3,201	$ 2,759
Accrued professional fees and other	1,455	670
Operating lease liability	389	-
Deferred rent	-	425
Total other accrued liabilities	$ 5,045	$ 3,854

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 PPARδ compounds (the PPARδ Products) with Janssen Pharmaceutical NV (Janssen NV), with the right to grant sublicenses to third parties to make, use and sell such PPARδ Products. Janssen NV has a right of first negotiation under the agreement to license particular patents covering the PPARδ Product(s) 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 PPARδ Products. Under the terms of the agreement Janssen NV is entitled to receive up to an 8% royalty on net sales of PPARδ Products. No amounts were incurred or accrued for this agreement as of and for the three or nine months ended September 30, 2019 and 2018.

In June 2010, the Company entered into two development and license agreements with Janssen Pharmaceuticals, Inc. (Janssen), a subsidiary of Johnson and Johnson, to further develop and discover undisclosed metabolic disease target agonists for the treatment of Type 2 diabetes and other disorders. The Company received a termination notice from Janssen, effectively ending these development and licensing agreements in early April 2015. In December 2015, the Company exercised an option, and Janssen granted the Company an exclusive, worldwide license with rights to sublicense, pursuant to the terms of one of the original agreements to continue to develop compounds with activity against an undisclosed metabolic disease target.

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 or nine months ended September 30, 2019 and 2018 and no royalties have been paid to date.

Kowa Pharmaceuticals America, Inc.

On December 30, 2016, the Company entered into a license agreement with Kowa. Pursuant to the license agreement, the Company granted to Kowa an exclusive license, and right to sublicense, certain patent rights and technology related to arhalofenate. Kowa had exclusive rights to, among other things, develop, use, manufacture, sell and otherwise exploit the licensed technology in the United States (including all possessions and territories). On October 24, 2018, the Company received a notice of Kowa's intent to terminate the license agreement for the development of arhalofenate. The termination was effective on January 22, 2019. As a result of the termination, the rights licensed to Kowa through the agreement reverted to the Company on the termination date and the Company is no longer eligible to receive additional milestone payments or royalties from Kowa.

5. Leases

The Company has one operating lease pertaining to 17,698 square feet of corporate office space in Newark, California pursuant to a lease agreement that commenced January 16, 2014 and was amended on April 16, 2018. At September 30, 2019 the Company's lease portfolio had a weighted average remaining term of 4.3 years, with an option to extend for an additional 5 years. The lease requires monthly lease payments that are subject to annual increases throughout the lease term. The optional period has not been considered in the determination of the right-of-use assets or lease liabilities associated with this lease as the Company did not consider it reasonably certain it would exercise the option.

The Company cannot determine the implicit rate in its lease, and therefore the Company uses its incremental borrowing rate as the discount rate when measuring operating lease liabilities. The incremental borrowing rate represents an estimate of the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of a lease within a particular currency environment. The Company used an incremental borrowing rate as of the date of adoption for leases that commenced prior to January 1, 2019. The weighted average discount rate for the Company's lease portfolio at September 30, 2019 was 12.6%.

For the three and nine months ended September 30, 2019, the Company incurred $0.2 million and $0.4 million of lease costs included in operating expenses in the condensed consolidated statements of income and comprehensive income in relation to its operating lease, a portion of which was variable rent expense and not included within the measurement of the Company's operating ROU assets and lease liabilities. The variable rent expense consists primarily of the Company's proportionate share of operating expenses, property taxes, and insurance and is classified as lease expense due to the Company's election to not separate lease and non-lease components. Short-term lease costs were not material. At September 30, 2019, the Company's operating lease right-of-use asset totaled $0.2 million, and the operating lease liability totaled $2.2 million. The short term portion of the operating lease liability was $0.3 million and is contained within other accrued liabilities on the balance sheet, with the remaining $1.9 million liability reported on the balance sheet as long-term portion of operating lease liability

Rent expense for the three and nine months ended September 30, 2018 was $0.1 million and $0.3 million, respectively, a portion of which represents immaterial variable rent expense.

As of September 30, 2019, the maturities of the Company's operating lease liabilities were as follows (in thousands):

	Operating Leases
Year ending December 31,	
2019 (from October to December)	$ 158
2020	647
2021	667
2022	686
2023	707
Thereafter	30
Total undiscounted future minimum lease payments	$ 2,895
Less: Imputed interest	655
Total operating lease liability	$ 2,240
Less: Current portion of operating lease liability (included in other accrued liabilities)	389
Long-term portion of operating lease liability	$ 1,851

6. Stockholders' Equity

On February 1, 2018, pursuant to a shelf registration statement on Form S-3, the Company issued 13,340,000 shares of its common stock at $10.80 per share in an underwritten public offering (referred to as the February 2018 public offering). Net proceeds to the Company from the February 2018 public offering were approximately $135.5 million after deducting underwriting discounts, commissions and other offering expenses.

On March 8, 2019, pursuant to a shelf registration statement on Form S-3, the Company issued 8,000,000 shares of its common stock at $12.50 per share in an underwritten public offering (referred to as the March 2019 public offering). On March 11, 2019, the underwriters fully exercised their option to purchase additional shares resulting in the issuance of an additional 1,200,000 shares. Net proceeds to the Company from the March 2019 public offering were approximately $107.7 million after deducting underwriting discounts, commissions and other offering expenses.

7. Stock Plan and Stock-Based Compensation

Stock Plan

In accordance with the provisions of the Company's 2013 Equity Incentive Plan (2013 Plan), the Board of Directors reduced the automatic increase in the share reserve to 2,378,259 shares, which were automatically available for issuance on January 1, 2019. During the three and nine months ended September 30, 2019, the Company granted options to purchase 589,600 and 2,733,960 shares, respectively, of its common stock to its employees and directors. As of September 30, 2019, there were1,249,186 shares available for grant under the 2013 Plan.

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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	$ 1,504	$ 741	$ 3,602	$ 2,045
General and administrative	1,361	987	3,881	3,230
Total stock-based compensation expense	$ 2,865	$ 1,728	$ 7,483	$ 5,275

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

Operating results for the three and nine months ended September 30, 2019, 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 clinical testing, and the timing of results thereof; regulatory submissions and approvals; 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 could differ materially from those anticipated in these forward-looking statements for many reasons, including as a result of the risks and uncertainties discussed under the heading "Risk Factors" in Item 1A of Part II of this Quarterly Report on Form 10-Q. Any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

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 (PPARδ), 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 are currently developing seladelpar to treat patients with chronic liver diseases including:

- Primary Biliary Cholangitis (PBC), a rare, chronic autoimmune disease that causes progressive destruction of the bile ducts in the liver resulting in impaired bile flow (cholestasis) and inflammation. The FDA has granted seladelpar Breakthrough Therapy Designation for the treatment of early stage PBC.
- Primary Sclerosing Cholangitis (PSC), a rare, chronic cholestatic liver disease characterized by diffuse inflammation and fibrosis of the intrahepatic and extrahepatic bile ducts.
- 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 October 2018, we commenced enrollment of a global, Phase 3 registration study (ENHANCE) to evaluate seladelpar in patients with PBC. The Phase 3 study is a double-blind, randomized, placebo-controlled 52-week study evaluating the safety and efficacy of 5 mg and 10 mg of seladelpar versus placebo in patients with PBC who have had an inadequate response or are intolerant to first-line treatment with ursodeoxycholic acid (UDCA). An inadequate response is defined as a patient having alkaline phosphatase (ALP) levels greater than 1.67 times the upper limit of normal (ULN). Approximately 240 patients will be randomized to receive placebo, 5 mg of seladelpar, or 10 mg of seladelpar. Patients on 5 mg will have the potential to increase the dose, in a double-blinded manner, to 10 mg after 6 months if they have not yet met the primary endpoint. The primary endpoint is a composite response defined as a patient achieving an ALP level below 1.67 times the upper limit of normal, with at least a 15% reduction from baseline, and a normal total bilirubin at 52 weeks. The primary analysis will compare response rates of treatment groups to those of the placebo. Key secondary endpoints will be ALP normalization rate and changes in pruritus, as measured by the numerical rating scale, or NRS. In early November, we announced that we had reached target enrollment of 240 patients. We expect the ENHANCE Phase 3 study to be fully enrolled by the end of November 2019 and anticipate reporting topline Phase 3 data in early 2021.

In February 2019, we completed enrollment of a placebo-controlled Phase 2b proof-of-concept study to evaluate seladelpar at three doses in biopsy-proven NASHThe double-blind, placebo-controlled study randomized 181 subjects with biopsy-confirmed NASH and a liver fat content (LFC) greater than 10% to receive either placebo or seladelpar 10 mg, 20 mg, or 50 mg once-daily. The enrolled subjects had established NASH with a mean NAFLD Activity Score of 5.2 at baseline, with 83% of subjects having stage 2 or stage 3 fibrosis. Other key baseline characteristics include a mean LFC by magnetic resonance imaging-proton density fat fraction (MRI-PDFF) of 21% as well as elevated mean levels of alanine aminotransferase (ALT) and aspartate aminotransferase (AST) of 62 U/L and 46 U/L, respectively. Approximately half of the subjects enrolled had a diagnosis of type 2 diabetes.

In June 2019, we released topline 12-week data from our Phase 2b NASH study. The primary endpoint was the relative change in LFC from baseline to 12 weeks. The study remains blinded and will continue to 52 weeks with assessments including a liver biopsy, non-invasive imaging evaluations, and biomarker assessments of inflammation and fibrosis. According to this data, treatment with seladelpar resulted in minimal reductions in liver fat as measured by MRI-PDFF that were not significant when compared to placebo. Treatment with seladelpar resulted in robust and clinically meaningful reductions in markers associated with liver injury. ALT declined up to 37.5% or 32 U/L in 12 weeks. These reductions in ALT are greater than the 17 U/L threshold that has been correlated with histologic improvement in NASH. Gamma glutamyl transferase (GGT) also decreased significantly, suggesting a reduction in hepatocellular oxidative stress. Significant reductions in ALP at 12 weeks were observed, supportive of a decrease in hepatocellular bile acids. We expect to announce 52-week topline data in the second quarter of 2020.

Also in June 2019, we announced plans for a Phase 2 study of seladelpar in patients with PSC. The planned Phase 2 study will be a randomized, placebo-controlled, dose-ranging study that will enroll approximately 100 patients at 60 sites globally. Seladelpar at doses of 5, 10, and 25 mg once daily will be studied versus placebo in a 1:1:1:1 randomization. The primary efficacy outcome will be the relative change in ALP from baseline at 24 weeks. The study includes an interim assessment of safety and efficacy after approximately 10 patients in each dose group reach 12 weeks of treatment. We initiated this study in the third quarter of 2019.

Equity Financings

On February 1, 2018, pursuant to our $200 million shelf registration statement on Form S-3, we completed the issuance of 13,340,000 shares of our common stock at $10.80 per share, which we refer to as our February 2018 public offering. Net proceeds from the February 2018 public offering were approximately $135.5 million after deducting underwriting discounts, commissions and other offering expenses.

On March 8, 2019, pursuant to a shelf registration statement on Form S-3, we issued 8,000,000 shares of our common stock at $12.50 per share in an underwritten public offering, which we refer to as the March 2019 public offering. On March 11, 2019, the underwriters fully exercised their option to purchase additional shares resulting in the issuance of an additional 1,200,000 shares. Net proceeds from the March 2019 public offering were approximately $107.7 million after deducting underwriting discounts, commissions and other offering expenses.

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 consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. We consider certain accounting policies including, but not limited to, revenue recognition, research and development expenses and clinical accruals, stock-based compensation and valuation of warrant liabilities to be critical policies. The preparation of these 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.

For further information on our significant accounting policies, refer to our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on February 28, 2019.

Results of Operations

General

As of September 30, 2019, we had an accumulated deficit of $596.5 million, primarily as a result of expenditures for research and development and general and administrative expenses from inception to that date. While we have historically generated revenue from license arrangements and may in the future generate revenue from a variety of other sources, including license fees and milestone payments in connection with any future strategic partnerships, seladelpar is at a mid-level stage of development and our other product candidates are at an early stage of development and may never be successfully developed 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. Our results of operations for the three and nine months ended September 30, 2019 and 2018 are presented below (in thousands):

	Three Months Ended September 30,		Change Q3	Nine Months Ended September 30,		Change Q3 YTD
	2019	2018	2019 vs 2018	2019	2018	2019 vs 2018
Operating expenses:						
Research and development	$ 23,193	$ 17,853	$ 5,340	$ 62,900	$ 41,727	$ 21,173
General and administrative	4,514	3,276	1,238	14,706	10,223	4,483
Total operating expenses	27,707	21,129	6,578	77,606	51,950	25,656
Loss from operations	(27,707)	(21,129)	(6,578)	(77,606)	(51,950)	(25,656)
Other income (expense):						
Interest income, net	1,425	1,113	312	4,211	2,546	1,665
Loss on extinguishment of debt	-	-	-	-	(407)	407
Other income (expense), net	-	1,453	(1,453)	-	(3,288)	3,288
Total other income (expense)	1,425	2,566	(1,141)	4,211	(1,149)	5,360
Net loss	$ (26,282)	$ (18,563)	$ (7,719)	$ (73,395)	$ (53,099)	$ (20,296)

Operating Expenses

Operating expenses consist of research and development and general and administrative expenses as presented in the table below (in thousands):

	Three Months Ended September 30,		Change Q3	Nine Months Ended September 30,		Change Q3 YTD
	2019	2018	2019 vs 2018	2019	2018	2019 vs 2018
Operating expenses:						
Research and development	$ 23,193	$ 17,853	$ 5,340	$ 62,900	$ 41,727	$ 21,173
General and administrative	4,514	3,276	1,238	14,706	10,223	4,483
Total operating expenses	$ 27,707	$ 21,129	$ 6,578	$ 77,606	$ 51,950	$ 25,656

Research & Development Expenses

Conducting research and development is central to our business model. We expect to continue to incur substantial expenses related to our development activities for the foreseeable future as we continue product development for seladelpar. Since product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later stage clinical trials, we expect that our research and development expenses will increase in the future.

For the three months ended September 30, 2019 and 2018, research and development expenses were $23.2 million and $17.9 million, respectively. For the nine months ended September 30, 2019 and 2018, research and development expenses were$62.9 and $41.7 million, respectively. Research and development expenses are detailed in the table below (in thousands):

	Three Months Ended September 30,		Change Q3	Nine Months Ended September 30,		Change Q3 YTD
	2019	2018	2019 vs 2018	2019	2018	2019 vs 2018
Project costs:						
Seladelpar PBC clinical studies	$ 8,920	$ 7,030	$ 1,890	$ 27,718	$ 15,884	$ 11,834
Seladelpar NASH clinical studies	2,635	5,780	(3,145)	7,993	10,207	(2,214)
Seladelpar PSC clinical studies	1,288	-	1,288	2,264	-	2,264
Seladelpar drug manufacturing & development	3,607	1,167	2,440	7,014	4,605	2,409
Seladelpar other studies	530	222	308	2,072	725	1,347
Non-seladelpar studies	14	43	(29)	284	97	187
Total project costs	16,994	14,242	2,752	47,345	31,518	15,827
Internal research and development costs	6,199	3,611	2,588	15,555	10,209	5,346
Total research and development	$ 23,193	$ 17,853	$ 5,340	$ 62,900	$ 41,727	$ 21,173

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 September 30, 2019 and 2018

Total project costs increased by $2.8 million to $17.0 million from $14.2 million for the three months ended September 30, 2019 and 2018, respectively. Project costs for the three months ended September 30, 2019 and 2018 consisted primarily of seladelpar-related clinical trial expenses. These increases were driven by higher manufacturing costs incurred to support our ongoing clinical trials and registration batches.

Internal research and development costs increased by $2.6 million to $6.2 million from $3.6 million for the three months ended September 30, 2019, as compared to the same period in 2018, primarily due to higher employee compensation related expenses as we hired additional clinical, scientific and regulatory personnel to support our expanding clinical development activities. We also incurred severance expense during the quarter due to the departure of an executive.

Comparison of Nine Months Ended September 30, 2019 and 2018

Total project costs increased by $15.8 million to $47.3 million from $31.5 million for the nine months ended September 30, 2019 and 2018, respectively. Project costs for the nine months ended September 30, 2019 consisted primarily of seladelpar-related clinical trial expenses. These increases were driven by ongoing enrollment activities related to our PBC Phase 3 clinical trial, startup activities related to our PSC Phase 2 clinical trial, and other NDA-enabling studies. The increased number and size of our clinical trials and the preparation of registration batches also resulted in higher manufacturing costs to support these activities. The overall increase in project costs was partially offset by decreased costs on our fully enrolled NASH Phase 2b study.

Internal research and development costs increased by $5.4 million to $15.6 million from $10.2 million for the nine months ended September 30, 2019, as compared to the same period in 2018, primarily due to higher employee compensation related expenses as we hired additional clinical, scientific and regulatory personnel to support our expanding clinical development activities. We also incurred severance expense during 2019 due to the departure of an executive.

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 September 30, 2019 and 2018

General and administrative expenses increased by $1.2 million to $4.5 million from $3.3 million for the three months ended September 30, 2019 and 2018, respectively. The increase was driven primarily by higher employee compensation and other administrative expenses incurred to support our expanding operations.

Comparison of Nine Months Ended September 30, 2019 and 2018

General and administrative expenses increased by $4.5 million to $14.7 million from $10.2 million for the nine months ended September 30, 2019 and 2018, respectively. The increase was driven primarily by higher employee compensation and other administrative expenses incurred to support our expanding operations.

Other Income (Expense)

Interest income, net consists primarily of interest income from our marketable securities offset in part by interest expense related to our loan facility. In connection with the early payoff of our term loan facility in June 2018, we recognized a $0.4 million loss on the extinguishment of debt. Other expense, net consists of gains and losses resulting from the remeasurement of our warrant liabilities at fair value. Other income (expense) is detailed below (in thousands):

	Three Months Ended September 30,		Change Q3	Nine Months Ended September 30,		Change Q3 YTD
	2019	2018	2019 vs 2018	2019	2018	2019 vs 2018
Other income (expense):						
Interest income, net	$ 1,425	$ 1,113	$ 312	$ 4,211	$ 2,546	$ 1,665
Loss on extinguishment of debt	-	-	-	-	(407)	407
Other income (expense), net	-	1,453	(1,453)	-	(3,288)	3,288
Total other income (expense)	$ 1,425	$ 2,566	$ (1,141)	$ 4,211	$ (1,149)	$ 5,360

Comparison of Three Months Ended September 30, 2019 and 2018

Interest income, net increased $0.3 million, due to our increased investments portfolio.

Other income, net decreased by $1.4 million to zero in 2019 due to the extinguishment of our common stock warrant liabilities in the third quarter of 2018. The income in the three months ended September 30, 2018 was driven by a gain on remeasurement of our warrant liabilities at fair value.

Comparison of Nine Months Ended September 30, 2019 and 2018

Interest income, net increased $1.7 million, due to higher interest earned on our investments portfolio and the extinguishment of our term loan in the second quarter of 2018. In prior periods, term loan interest expense offset interest income derived from our investments in marketable securities.

Other expense, net decreased by $3.3 million to zero in 2019, primarily due to the extinguishment of our common stock warrant liabilities in the third quarter of 2018. The expense in the nine months ended September 30, 2018 was driven by a loss on remeasurement of our warrant liabilities at fair value.

Liquidity and Capital Resources

We have generated significant operating losses since our inception due to our continuing research and development activities. We have financed our operations primarily through the sale of equity securities, licensing fees, issuance of debt and collaborations with third parties. At September 30, 2019, we had cash, cash equivalents and marketable securities of $218.6 million, compared to $178.7 million at December 31, 2018. 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, and U.S. treasury 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 2021.

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

Term Loan Facility

On August 7, 2015, we entered into a Loan and Security Agreement, pursuant to which we refinanced our previous term loan facility with Oxford Finance LLC and Silicon Valley Bank, and we borrowed an aggregate of $10.0 million, of which $5.9 million was outstanding on December 31, 2017. From January through June 1, 2018, we paid $1.6 million of principal payments due under its term loan facility. On June 4, 2018, we repaid in full the outstanding balance of the 2015 term loan facility of $4.2 million plus a final fee of $0.7 million and a prepayment penalty of $0.1 million. In conjunction with this prepayment, we recorded $0.4 million loss on extinguishment of debt. We have no further obligations under this agreement as a result of this prepayment.

Cash Flows

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

	Nine Months Ended September 30,	
	2019	**2018**
Net cash used in operating activities	$ (69,775)	$ (35,341)
Net cash used in investing activities	(43,608)	(80,882)
Net cash provided by financing activities	107,850	134,964
Net (decrease) increase in cash and cash equivalents	$ (5,533)	$ 18,741

Operating Activities: Net cash used in operating activities for the nine months ended September 30, 2019 increased by $34.5 million to $69.8 million as compared to $35.3 million for the same period in the prior year, partially due to an increase in our net loss to $73.4 million as a result of our expanding drug development activities and the timing of payments to our vendors. Additionally, cash used in the nine months ended September 30, 2018 was offset by the collection of a $5 million collaboration receivable and a $3.7 million adjustment to remove a non-cash loss recorded to revalue our warrant liability, without similar collections or non-cash activity in the same period of 2019.

Investing Activities: Net cash used in investing activities was $43.6 million for the nine months ended September 30, 2019 compared to $80.9 million for the same period in the prior year, primarily due to the timing of our investments in marketable securities.

Financing Activities: Net cash provided by financing activities was $107.9 million for the nine months ended September 30, 2019 compared to $135.0 million for the same period in the prior year. The overall decrease in 2019 was primarily due to the smaller size of our March 2019 public offering as compared to our February 2018 public offering.

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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Overview

We are exposed to market risk in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of fluctuations in interest rates and foreign currency exchange rates. We do not hold or issue financial instruments for trading purposes.

Interest Rate Sensitivity

Our exposure to market risk for changes in interest rates relates primarily to our cash, cash equivalents, and investments. We had cash, cash equivalents, and investments of $218.6 million as of September 30, 2019, compared to $178.7 million at December 31, 2018. As of September 30, 2019 and December 31, 2018, we held our cash, cash equivalents, and investments in marketable securities in deposits, money market funds, corporate debt, commercial paper, asset-backed securities, and U.S. treasury securities. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of the interest rates. Therefore, a portion of our investments may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our investments are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio as of September 30, 2019, or December 31, 2018. We actively monitor changes in interest rates. We do not hold investments for trading purposes.

Foreign Exchange

We conduct our operations primarily in the United States using the U.S. Dollar. However, we conduct limited operations in foreign countries, primarily for clinical and regulatory services, whereby settlement of our obligations is denominated in the local currency. Transactional exposure arises when transactions occur in currencies other than the U.S. Dollar. We record transactions denominated in foreign currencies at the exchange rate prevailing at the date of the transaction with the resulting liabilities being translated into the U.S. Dollar at exchange rates prevailing at the balance sheet date. The resulting gains and losses, which were insignificant for the three and nine months ended September 30, 2019 and 2018, are included in other expense in the condensed consolidated statements of operations and comprehensive loss. We do not use currency forward exchange contracts to offset the related effect on the underlying transactions denominated in foreign currencies.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation as of September 30, 2019 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 September 30, 2019.

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 September 30, 2019, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1.

A. 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.

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 September 30, 2019, we had cash, cash equivalents and marketable securities of approximately $218.6 million, which we believe is sufficient to fund our current operating plan into 2021. If appropriate opportunities become available, we intend to seek to raise additional equity and/or debt capital to fund our continued operations, including clinical trials and other product development. 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. We expect our expenses to increase in connection with our ongoing activities, particularly as we advance development of our lead clinical product candidate seladelpar (MBX-8025).

In the event we do not successfully raise sufficient funds in financing our product development activities, particularly related to the ongoing development of seladelpar, it will be necessary to curtail our product development activities commensurate with the magnitude of the shortfall or our product development activities may cease altogether. To the extent that the costs of the ongoing development of seladelpar 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, enter into a collaboration or other similar arrangement with respect to development and/or commercialization rights to seladelpar, out-license intellectual property rights to seladelpar, sell assets 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. Failure to progress the development of seladelpar will have a negative effect on our business, future prospects and ability to obtain further financing on acceptable terms (if at all).

Beyond the plan of operations outlined above, 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, including in particular the Phase 2 and Phase 3 studies of seladelpar;
- 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 U.S. Food and Drug Administration (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 and 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 our 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, our product candidates. We do not anticipate generating revenues from sales of our product candidates for the foreseeable future, if ever. Our ability to generate revenues from product sales depends heavily on our success in:

- obtaining favorable clinical trial results for, and advancing the development of, seladelpar; and
- 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 U.S. 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 intend to 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. For example, in July 2017 we completed the issuance of 14,950,000 shares of our common stock at a public offering price of $6.50 per share, in February 2018, we completed the issuance of 13,340,000 shares of our common stock at a public offering price of $10.80 in underwritten public offerings and in March 2019, we completed the issuance of 9,200,000 shares of our common stock at a public offering price of $12.50 in underwritten public offerings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interests of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, and declaring dividends, and may impose limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

If we raise additional funds through collaborations, strategic alliances, 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 and we may not be able to meet our debt service obligations. 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.

We have incurred and will continue to incur increased costs as a result of operating as a public company, and we will devote substantial time to meet compliance obligations.

We have incurred and will continue to incur legal, accounting and other expenses as a result of operating as a public company. We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and the Nasdaq Stock Market, or Nasdaq, that impose significant requirements on public companies, including requiring the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. Ensuring that we have adequate internal financial and accounting controls and procedures in place is a costly and time-consuming effort that needs to be re-evaluated from time to time. We expect to incur expense and devote management effort toward ensuring compliance with Section 404 of the Sarbanes-Oxley Act, or Section 404, including but not limited to system and process evaluation and testing of our internal controls over financial reporting, as required by Section 404. Pursuant to Section 404(c) of the Sarbanes-Oxley Act, our independent registered public accounting firm is required to deliver an attestation report on the effectiveness of our internal control over financial reporting. Our future testing may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Implementing certain appropriate changes to our internal controls may require specific compliance training for our directors, officers and employees, entail substantial costs to modify our existing accounting systems, and take a significant period of time to complete. Such changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate consolidated financial statements or other reports on a timely basis, could increase our operating costs and could materially impair our ability to operate our business. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent fraud. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal controls that are deemed to be material weaknesses, the market price of our stock could decline and/or we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

The 2017 U.S. tax legislation and future changes to applicable U.S. tax laws and regulations may have a material adverse effect on our business, financial condition and results of operations.

Changes in laws and policy relating to taxes may have an adverse effect on our business, financial condition and results of operations. For example, the U.S. government enacted significant tax reform in December 2017, and certain provisions of the new law may adversely affect us. Changes include, but are not limited to, a federal corporate tax rate decrease to 21% for tax years beginning after December 31, 2017, a reduction to the maximum deduction allowed for net operating losses generated in tax years after December 31, 2017, eliminating carrybacks of net operating losses, and providing for indefinite carryforwards for losses generated in tax years after December 31, 2017. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections and will be subject to interpretations and implementing regulations by the Treasury and Internal Revenue Service, any of which could mitigate or increase certain adverse effects of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation. Generally, future changes in applicable U.S. tax laws and regulations, or their interpretation and application could have an adverse effect on our business, financial conditions and results of operations.

Risks Related to Clinical Development and Regulatory Approval

We depend on the success of our product candidates, in particular seladelpar, which is still under clinical development and we may not obtain regulatory approval or successfully commercialize this product candidate.

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, including seladelpar, which has completed multiple Phase 1 and Phase 2 clinical trials. There is no guarantee that our clinical trials will be completed or, if completed, will be successful. In July 2017, April 2018, and November 2018, we announced positive interim results from an ongoing low-dose Phase 2 study of seladelpar in patients with primary biliary cholangitis, or PBC. During the fourth quarter of 2017, we initiated enrollment in a long-term extension study of seladelpar in patients with PBC. In February 2019, we completed enrollment in a Phase 2b study of seladelpar in patients with nonalcoholic steatohepatitis, or NASH and in June 2019 we announced interim results in that ongoing study. In October 2018 we commenced enrollment of a global Phase 3 study to evaluate seladelpar in patients with PBC and we expect to complete enrollment of this study by the end of November 2019. We initiated a Phase 2 clinical study of seladelpar in patients with primary sclerosing cholangitis, or PSC in the third quarter of 2019. The success of seladelpar will depend on many factors, including the following:

- successful enrollment and completion of clinical trials;
- recognition by the FDA and other regulatory authorities outside of the United States of orphan disease designation for seladelpar in target indications in addition to those already obtained;
- receipt of marketing approvals from the FDA and regulatory authorities outside the United States for seladelpar;

- 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 seladelpar, which would materially harm our business.

We depend on the successful completion of clinical trials for our product candidates, including seladelpar. The positive clinical results obtained for our product candidates in prior clinical studies may not be repeated in future clinical studies.

Before obtaining regulatory approval for the sale of our product candidates, including seladelpar, 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 have completed numerous Phase 1 and Phase 2 clinical studies with seladelpar. However, we have not completed a Phase 3 clinical trial, have never obtained regulatory approval for a drug and we may be unable to obtain, or may be delayed in obtaining, initial or full regulatory approval for seladelpar. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed satisfactorily through preclinical studies and initial clinical testing. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience, have suffered significant setbacks in Phase 3 clinical development, even after seeing promising results in earlier clinical trials.

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;
- 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.

We expect our expenses to increase in connection with our ongoing activities, particularly as we undertake additional clinical trials of seladelpar. We also will need to raise substantial additional capital in the future to complete the development and commercialization of seladelpar. Because successful development of our 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 seladelpar, or any other clinical trial we conduct, 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.

We have commenced clinical trials to test seladelpar for the treatment of PBC, PSC and NASH. If seladelpar does not demonstrate safety or efficacy in these indications, or if the benefits of treatment with seladelpar do not outweigh the risks, our ability to successfully develop and commercialize seladelpar may be adversely affected.

We commenced clinical trials of seladelpar for the indications for PBC, PSC and NASH. Seladelpar may not be demonstrated to be effective in these indications or other indications we may target. Although we believe that seladelpar may be beneficial to address PBC, PSC and/or NASH, there is no guarantee that seladelpar will prove to be safe or efficacious in the treatment of these diseases, or that we will be able to obtain regulatory approval for these indications. The results of these clinical studies and other nonclinical studies may determine whether the benefits perceived from the use of seladelpar would outweigh the risks perceived from treatment with seladelpar.

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. Our planned clinical trials 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, including our future clinical trials for seladelpar, 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 subjects dropping out of a trial due to side effects or otherwise;
- changes to treatment guidelines or the introduction of a new standard of care;
- delays caused by clinical sites dropping out of a trial;
- time required to add new clinical sites;
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials; and
- delays in importing clinical trial materials into foreign countries where our clinical trials are being conducted.

If initiation or completion of any of our clinical trials for our product candidates, including seladelpar, 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 from a Phase 2 clinical study of seladelpar in patients with PBC. During the course of this trial three cases of asymptomatic, reversible transaminase elevations occurred, and we made the decision to discontinue the study early after review of safety and efficacy data demonstrated a need for further dose reduction to optimize clinical safety and efficacy. The emergence of adverse events (AEs) caused by seladelpar in future studies, including at lower doses, could cause us, other reviewing entities, clinical study sites or regulatory authorities to interrupt, delay or halt clinical studies and could result in the denial of regulatory approval. There is also a risk that our other product candidates may induce AEs, many of which may be unknown at this time. If an unacceptable frequency and/or severity of AEs are reported in our clinical trials for our product candidates, our ability to obtain regulatory approval for product candidates, including seladelpar, may be negatively impacted.

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.

We have obtained orphan drug designation for seladelpar for the treatment of PBC, but not for all possible indications for which we may seek approval and we may not be able to obtain or maintain orphan designation or obtain the benefits associated with orphan drug status, including market exclusivity.

Regulatory authorities in some jurisdictions, including the United States and the European Union, or EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, as amended, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA or the European Medicines Agency, or EMA, from approving another marketing application for the same drug for that time period. The applicable period is seven years in the United States and ten years in the European Union. The EU exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. In addition, the orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process. Also, regulatory approval for any product candidate may be withdrawn and other candidates may obtain approval before us.

We have obtained orphan-drug designations for seladelpar for the treatment of PBC by both the FDA and EMA. These exclusivities, or any other orphan exclusivity we may receive for another product candidate or indication, may not effectively protect the candidate from competition because: different drugs can be approved for the same condition; the same drugs can be approved for different indications and prescribed off-label; and the first entity with an orphan drug designation to receive regulatory approval for a particular indication will receive marketing exclusivity. If one of our product candidates that receives an orphan drug designation, including seladelpar, is approved for a particular indication or use within the rare disease or condition, the FDA may later approve the same product for additional indications or uses within that rare disease or condition that are not protected by our exclusive approval. Even after an orphan drug is approved, the FDA can subsequently approve another drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer in a substantial portion of the target population, more effective or makes a major contribution to patient care. Additionally, the EMA can withdraw its orphan-drug designation even after market authorization if it determines that the drug has not demonstrated a significant benefit over other drugs for the same condition.

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 seladelpar or any other 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 such as seladelpar;
- 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.

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.

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

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

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

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

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

We cannot commercialize our product candidates, including seladelpar, 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, including seladelpar. 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 seladelpar or our other 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 seladelpar and our other product candidates or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. For example, the labeling ultimately approved for our product candidates, including seladelpar, may include restrictions on use due to the specific patient population and manner of use in which the drug was evaluated and the safety and efficacy data obtained in those evaluations. In addition, we expect the approval pathway for seladelpar for treatment of PBC and/or NASH to be governed by Subpart H of the Food and Drug Act. As such, any approvals will initially be conditional and require confirmatory trials.

Seladelpar and our other product candidates will also be subject to additional ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping and reporting of safety and other post-market information. The holder of an approved NDA is obligated to monitor and report AEs and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. Furthermore, promotional materials must be approved by the FDA prior to use for any drug receiving accelerated approval.

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

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

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

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize seladelpar and our other 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 seladelpar or any of our other product candidates in the United States, we may never obtain approval for or commercialize seladelpar or any of our other 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.

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 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 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 following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal health care programs such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the 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, imposes criminal and civil liability for executing a scheme to defraud any health care benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services;
- the federal transparency requirements under the PPACA, commonly referred to as the Physician Payments Sunshine Act, require manufacturers of drugs, devices, biologics and medical supplies to report to the Centers for Medicare and Medicaid Services (CMS) payments and other transfers of value provided to physicians and teaching hospitals and ownership and investment interests held by physicians and other healthcare providers and their immediate family members in certain manufacturers and group purchasing organizations; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving health care items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring manufacturers to report information related to payments to physicians and other health care providers, marketing expenditures, or drug pricing. Certain state and local laws also require the registration of pharmaceutical sales representatives. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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 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 Patient Protection and Affordable Care Act (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. The PPACA revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. New provisions affecting compliance have also been enacted, which may affect our business practices with health care practitioners. 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. Since January 2017, President Trump has signed two 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 has 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 such as removing penalties, starting January 1, 2019, for not complying with the PPACA's individual mandate to carry health insurance, delaying the implementation of certain PPACA-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the PPACA will impact the PPACA and our business. Although the full effect of the PPACA remains uncertain, it appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. 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.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. In August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction, or joint committee, to recommend proposals in spending reductions to Congress. The joint committee did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013 and, due to subsequent legislative amendments, will remain in effect through 2027 unless additional congressional action is taken. In January 2013, the President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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 released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. HHS has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. On January 31, 2019, the HHS Office of Inspector General proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. While some of these and other proposed measures may require additional authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. 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.

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 plan on entering 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 the drug substance for seladelpar and our other product candidates, and any disruption in the chain of supply may cause delay in developing and commercializing for each product candidate, including seladelpar.

It is our current expectation that only one supplier of drug substance for seladelpar and one supplier of drug product for seladelpar will be initially qualified by the FDA. 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.

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

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

- the inability to meet our product specifications, including product formulation, and quality requirements consistently;
- a delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues, including those related 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;
- 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 clinical study delays, failure to obtain regulatory approval or impact our ability to successfully commercialize our products. Some of these events could be the basis for FDA or other regulatory authorities' action, including injunction, recall, seizure, or total or partial suspension of production.

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

We rely on contract service providers (CSPs) including clinical research organizations, clinical trial sites, central laboratories and other service providers to ensure the proper and timely conduct of our clinical trials. While we have agreements governing their activities, we have limited influence over their actual performance. We have relied and plan to continue to rely upon CSPs to monitor and manage data for our ongoing 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 Conference on 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 seladelpar and our other product candidates 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, including seladelpar, receive marketing approval, they may nonetheless be unable to gain sufficient market acceptance by physicians, patients, health care payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any of our product candidates, including seladelpar, 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, including seladelpar, 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. In addition, approval of seladelpar in multiple indications (such as PBC and NASH), or the approval of other drugs in NASH that might be effective in PBC could lead to negative pricing pressure on any commercialization of seladelpar in PBC, which could have a material adverse effect on our financial condition.

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, including seladelpar, 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, including seladelpar.

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 seladelpar, 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 seladelpar to market or generate product revenue.

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

In addition, there are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product 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 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.

Formulary approval and reimbursement may not be available for seladelpar, which could make it difficult for us to sell our products profitably.

Inclusion of seladelpar on insurance carrier or health plan lists of preferred drugs, sometimes referred to as formularies, may not be possible or may become an expensive and time consuming process. We cannot be certain if and when we will obtain formulary approval in our target markets. Failure to obtain timely formulary approval will limit our commercial success.

Furthermore, market acceptance and sales of seladelpar or any other product candidates that we or our collaborators develop, will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A prevailing trend in the U.S. health care industry and elsewhere is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. We cannot be sure that reimbursement will be available for seladelpar, or any other product candidates. Also, reimbursement amounts may reduce the demand for, or the price of, our products. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize seladelpar, or any other product candidates that we develop.

The availability of generic treatments may also substantially reduce the likelihood of reimbursement for any future products, including seladelpar. The application of user fees to generic drug products will likely expedite the approval of additional generic drug treatments. We expect to experience pricing pressures in connection with the sale of seladelpar and any other product candidate that we develop, due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes.

In addition, there may be significant delays in obtaining reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or health authorities in other countries. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government health care programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but also have their own methods and approval process apart from Medicare determinations.

If we are unable to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any of our product candidates, including seladelpar, it could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Even if we receive regulatory approval for seladelpar, we will be subject to ongoing FDA and other regulatory obligations and continued regulatory review, which may result in significant additional expense and limit our ability to commercialize seladelpar.

Any regulatory approvals that we or potential collaboration partners receive for seladelpar or future product candidates, may also be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing studies. For example, we expect the approval pathway for seladelpar for the treatment of PBC and/or NASH to be governed by Subpart H of the Food and Drug Act. As such, any approvals will initially be conditional and require confirmatory trials. Such trials may be costly and time consuming and may be unsuccessful in confirming the benefits of the conditionally approved product, potentially resulting in the withdrawal of approval and withdrawal of the product from the market. In addition, even if approved, the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for any product will be subject to extensive and ongoing regulatory requirements. The subsequent discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, may result in restrictions on the marketing of the product, and could include withdrawal of the product from the market. Depending on any safety issues associated with our product candidates that are approved, the FDA may require a REMS plan, thereby imposing certain restrictions on the sale and marketability of such products or additional post-marketing requirements.

Regulatory policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we might not be permitted to market seladelpar or future products, if any, and we may not achieve or sustain profitability.

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

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical studies, and will face an even greater risk if we sell our product candidates 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 do 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.

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

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

We are a party to a number of technology licenses that are important to our business and 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 PPARδ compounds (the PPARδ Products). Under the exclusive license with Janssen NV we have full control and responsibility over the research, development and registration of any PPARδProducts 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 PPARδ 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 PPARδ 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 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 agreements or 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 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 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 strategy. Our consultants and advisors may be employed 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.

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As our company matures, we expect to expand our employee base to increase our managerial, clinical, scientific and engineering, operational, sales, and marketing teams. Future growth would impose significant 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 disproportionate amount of its 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 remaining employees. Our expected growth could require significant 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 generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our 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. 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 were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs and our reputation could be materially damaged. We would 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 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 is likely to increase 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, may impose 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.

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 application (IND) 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 of our collaboration partners to elect to develop or commercialize product candidates under our collaboration agreements or the termination of any programs under our collaboration agreements;
- 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 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;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future; and
- trading volume of our common stock.

In addition, companies trading in the stock market in general have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

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

We expect that significant additional capital will be needed in the future to continue our planned product development efforts, in particular clinical trial, 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. For example, in July 2017 we completed the issuance of 14,950,000 shares of our common stock at a public offering price of $6.50 per share in an underwritten public offering for net proceeds to us of approximately $91.1 million. In February 2018 we completed the issuance of 13,340,000 shares of our common stock at a public offering price of $10.80 per share in an underwritten public offering for net proceeds to us of approximately $135.5 million. In addition, in December 2018 we filed a $200 million shelf registration statement on Form S-3 with the SEC and in March 2019 we completed the issuance of 9,200,000 shares of our common stock at a public offering price of $12.50 per share in an underwritten public offering off of this shelf registration statement for net proceeds to us of approximately $107.7 million. 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 October 31, 2019, was 1,245,786 shares.

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

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

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

Our share price is volatile, and in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

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.

Item 6. Exhibits

Exhibit Number	Description of Document
3.1	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).
3.2	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).
4.1	Reference is made to Exhibits 3.1 and 3.2.
31.1	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.
31.2	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.
32.1	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.
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: November 5, 2019

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

Date: November 5, 2019

Exhibit 31.1

CERTIFICATIONS

I, Sujal Shah, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 5, 2019

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

Exhibit 31.2

CERTIFICATIONS

I, Daniel Menold, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 5, 2019

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

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), each of Sujal Shah, President and Chief Executive Officer, and Daniel Menold, Vice President, Finance of CymaBay Therapeutics, Inc. (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2019, 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 November 5, 2019.

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