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 June 30, 2018

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.)**
7999 Gateway Blvd, Suite 130 Newark, CA	**94560**
(Address of principal executive offices)	**(Zip Code)**

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

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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	☐ (Do not check if a smaller reporting company)	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 July 31, 2018, there were 59,052,798 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)

	June 30, 2018 (unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 44,726	$ 23,054
Marketable securities	167,353	74,156
Receivable from collaboration	-	5,000
Accrued interest receivable	405	103
Prepaid expenses	2,131	1,208
Other current assets	2,100	23
Total current assets	216,715	103,544
Property and equipment, net	90	69
Other assets	1,363	634
Total assets	$ 218,168	$ 104,247
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,336	$ 1,311
Accrued clinical trial expenses	7,877	2,929
Warrant liability	5,632	6,091
Other accrued liabilities	2,071	2,828
Facility loan	-	3,108
Accrued interest payable	-	43
Total current liabilities	16,916	16,310
Facility loan, less current portion	-	2,990
Deferred rent, net of current portion	2,039	-
Total liabilities	18,955	19,300
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; 58,959,936 and 44,408,796 shares issued and outstanding as of June 30, 2018 and December 31, 2017, respectively	6	4
Additional paid-in capital	684,326	535,503
Accumulated other comprehensive loss	(67)	(44)
Accumulated deficit	(485,052)	(450,516)
Total stockholders' equity	199,213	84,947
Total liabilities and stockholders' equity	$ 218,168	$ 104,247

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Collaboration revenue	$ -	$ -	$ -	$ 4,793
Operating expenses:				
Research and development	14,397	4,044	23,874	8,085
General and administrative	3,574	3,582	6,947	7,283
Total operating expenses	17,971	7,626	30,821	15,368
Loss from operations	(17,971)	(7,626)	(30,821)	(10,575)
Other income (expense):				
Interest income	1,061	44	1,769	81
Interest expense	(128)	(283)	(336)	(588)
Loss on extinguishment of debt	(407)	-	(407)	-
Other expense, net	(86)	(1,064)	(4,741)	(3,198)
Net loss	$ (17,531)	$ (8,929)	$ (34,536)	$ (14,280)
Net loss	$ (17,531)	$ (8,929)	$ (34,536)	$ (14,280)
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities	65	1	(23)	-
Other comprehensive income (loss)	65	1	(23)	-
Comprehensive loss	$ (17,466)	$ (8,928)	$ (34,559)	$ (14,280)
Basic net loss per common share	$ (0.30)	$ (0.31)	$ (0.61)	$ (0.52)
Diluted net loss per common share	$ (0.30)	$ (0.31)	$ (0.61)	$ (0.52)
Weighted average common shares outstanding used to calculate basic net loss per common share	58,833,647	28,752,451	56,307,236	27,687,110
Weighted average common shares outstanding used to calculate diluted net loss per common share	58,905,898	28,752,451	56,307,236	27,687,110

See accompanying notes to the condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2018	**2017**
Operating activities		
Net loss	$ (34,536)	$ (14,280)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	25	18
Stock-based compensation expense	3,547	3,118
Net accretion and amortization of investments in marketable securities	(777)	4
Non-cash interest associated with debt discount accretion	148	232
Loss on extinguishment of debt	407	-
Change in fair value of warrant liability	4,741	3,198
Accretion of tenant improvement allowance	(61)	-
Changes in assets and liabilities:		
Receivable from collaboration	5,000	-
Interest receivable and other current assets	(279)	4
Prepaid expenses	(923)	243
Other assets	(729)	(50)
Accounts payable	25	202
Accrued liabilities	4,191	(772)
Accrued interest payable	(43)	(11)
Net cash used in operating activities	(19,264)	(8,094)
Investing activities		
Purchases of property and equipment	(46)	-
Purchases of marketable securities	(185,925)	(9,822)
Proceeds from maturities of marketable securities	93,482	9,100
Net cash used in investing activities	(92,489)	(722)
Financing activities		
Proceeds from issuance of common stock, net of issuance costs	135,520	9,364
Proceeds from issuance of common stock pursuant to equity award plans	3,521	-
Proceeds from issuance of common stock upon exercise of warrants	1,037	-
Repayment of facility loan principal	(6,527)	(1,534)
Payment of fees to extinguish facility loan	(126)	-
Net cash provided by financing activities	133,425	7,830
Net increase (decrease) in cash and cash equivalents	21,672	(986)
Cash and cash equivalents at beginning of period	23,054	10,495
Cash and cash equivalents at end of period	$ 44,726	$ 9,509
Supplemental disclosure		
Cash paid for interest	$ 231	$ 367
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	$ 5,200	$ -

See accompanying notes to the condensed consolidated financial 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 two key clinical development candidates are seladelpar (MBX-8025) and arhalofenate. Seladelpar is currently being developed for the treatment of primary biliary cholangitis (PBC) and the Company is also developing seladelpar for the treatment of nonalcoholic steatohepatitis (NASH). Arhalofenate is being developed for the treatment of gout and has been out-licensed in the United States. 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 six months ended June 30, 2018, the Company incurred a net loss of $34.5 million and used $19.3 million of cash in operations. At June 30, 2018, the Company had an accumulated deficit of $485.1 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 partnered 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.

From January through June 1, 2018, the Company paid $1.6 million of principal payments due under its term loan facility with Oxford Finance LLC and Silicon Valley Bank. On June 4, 2018, the Company repaid in full the remaining outstanding balance of the 2015 Term Loan Facility of $4.2 million plus a final fee of $0.7 million (See Note 5).

As of June 30, 2018, the Company's cash, cash equivalents and marketable securities totaled $212.1 million. The Company believes these funds are sufficient to fund the Company's 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, the ongoing Phase 2b clinical trial activities in NASH, and most significantly, the timing and conduct of additional PBC development activities, including an ongoing Phase 2 clinical trial, a planned Phase 3 clinical trial, and 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; its existing license and collaboration arrangement with Kowa Pharmaceutical America, Inc. (Kowa); 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 the Company's 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 subsidiary. These unaudited interim condensed consolidated financial statements have been prepared in accordance with U.S. GAAP (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. "Accrued clinical trial expenses" and "Other accrued liabilities", which previously were reported as "Accrued liabilities" 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, 2017, which is contained in the Company's Annual Report on Form 10-K as filed with the SEC on March 15, 2018. The results for the six months ended June 30, 2018 are not necessarily indicative of results to be expected for the entire year ending December 31, 2018 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 actual future outcomes, and management must select an amount that falls within that range of reasonable estimates. Actual results could differ materially from those estimates. The Company believes significant judgment is involved in estimating revenue, stock-based compensation, accrued clinical expenses, and warrant liabilities.

Fair Value of Financial Instruments

The Company's financial instruments during the periods reported consist of cash and cash equivalents, marketable securities, accounts receivable, prepaid expenses, other current assets, accounts payable, accrued interest payable, accrued expenses, the facility loan, and warrant liabilities. 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, accounts receivable, prepaid expenses, other current assets, accounts payable, accrued expenses, and accrued interest payable approximate the related fair values due to the short maturities of these instruments. Based on prevailing borrowing rates available to the Company for loans with similar terms, the Company believes the fair value of the facility loan at December 31, 2017, considering level 2 inputs, approximates its carrying value.

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 June 30, 2018			
Description	**Level 1**	**Level 2**	**Level 3**	**Fair Value**
Cash equivalents:				
Money market funds	$ 41,017	$ -	$ -	$ 41,017
Commercial paper		2,989	-	2,989
Total cash equivalents	41,017	2,989	-	44,006
Marketable securities:				
Commercial paper	-	76,743	-	76,743
Corporate debt securities	-	47,143	-	47,143
Asset-backed securities	-	31,003	-	31,003
U.S. treasury securities	-	12,464	-	12,464
Total short-term investments	-	167,353	-	167,353
Total assets measured at fair value	$ 41,017	$ 170,342	$ -	$ 211,359
Warrant liability	$ -	$ -	$ 5,632	$ 5,632
Total liabilities measured at fair value	$ -	$ -	$ 5,632	$ 5,632

Description	As of December 31, 2017 Level 1	Level 2	Level 3	Fair Value
Cash equivalents:				
Money market funds	$ 12,822	$ -	$ -	$ 12,822
Commercial paper	-	6,035	-	6,035
Total cash equivalents	12,822	6,035	-	18,857
Marketable securities:				
Commercial paper	-	35,886	-	35,886
Corporate debt securities	-	19,760	-	19,760
Asset-backed securities	-	11,060	-	11,060
U.S. treasury securities	-	7,450	-	7,450
Total short-term investments	-	74,156	-	74,156
Total assets measured at fair value	$ 12,822	$ 80,191	$ -	$ 93,013
Warrant liability	$ -	$ -	$ 6,091	$ 6,091
Total liabilities measured at fair value	$ -	$ -	$ 6,091	$ 6,091

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.

The Company holds 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 are accounted for as liabilities. Beginning in September 2017, the Company changed its valuation technique and began to value its warrant liability using a Black-Scholes option pricing model, the inputs for which include: exercise price of the warrants, market price of the underlying common shares, dividend yield, expected term, expected volatility, and a risk-free interest rate. Changes to any of these inputs can have a significant impact on the estimated fair value of the warrants.

Historically, the Company used a binomial option pricing model to value its warrant liabilities. The inputs for the binomial model are similar to the Black-Scholes model but also incorporate other more complex inputs that, in the Company's case, have previously included the expected timing, probability and valuation impact of certain potential strategic events. Management concluded that no potential strategic events were expected to occur that, upon their announcement, could significantly impact the warrant liabilities valuation prior to their expiration beginning in late 2018 and ending in early 2019.

The following table sets forth an activity summary which includes the changes in the fair value of the Company's Level 3 financial instruments (in thousands):

	For the Six Months Ended June 30, 2018	2017
Balance, beginning of period	$ 6,091	$ 1,145
Issuance of financial instruments	-	-
Change in fair value	4,741	3,198
Settlement of financial instruments	(5,200)	-
Balance, end of period	$ 5,632	$ 4,343

Cash Equivalents and Marketable Securities

The Company considers all highly liquid investments with a remaining maturity of 90 days or less at the time of purchase to be cash equivalents. Cash and cash equivalents consist of deposits with commercial banks in checking, interest-bearing, demand money market accounts, corporate debt securities, 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 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 statements of operations and comprehensive loss. Unrealized holding gains and losses are reported in accumulated other comprehensive loss in the 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 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
As of June 30, 2018:				
Commercial paper	76,745	-	(2)	76,743
Corporate debt securities	47,198	-	(55)	47,143
Asset-backed securities	31,008	3	(8)	31,003
U.S. treasury securities	12,469	-	(5)	12,464
	$ 167,420	$ 3	$ (70)	$ 167,353

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
As of December 31, 2017:				
Commercial paper	35,886	-	-	35,886
Corporate debt securities	19,785	-	(25)	19,760
Asset-backed securities	11,070	-	(10)	11,060
U.S. treasury securities	7,459	-	(9)	7,450
	$ 74,200	$ -	$ (44)	$ 74,156

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 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 U.S. Food and Drug Administration (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 leases office space facilities under non-cancelable operating lease agreements and recognizes 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, are recognized as reductions to rental expense on a straight-line basis over the term of the lease. Lessor funded leasehold improvement incentives not yet received are recorded in other current assets on the balance sheet. The Company does not assume renewals in its determination of the lease term unless they are deemed to be reasonably assured at the inception of the lease and begins recognizing rent expense on the date that it obtains the legal right to use and control the leased space. Deferred rent consists of the difference between cash payments and the rent expense recognized.

Revenue Recognition

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

The Company enters into collaboration arrangements, under which it licenses certain rights to its intellectual property to third parties. The terms of these agreements may include payment to the Company of one or more of the following: nonrefundable, upfront license fees; development and commercial milestone payments; funding of research and/or development activities; and royalties on net sales of licensed products. Revenues that result from these payments are classified as collaborative revenues except for royalties on net sales of licensed products, which are classified as royalty revenues.

For each collaboration agreement that results in revenues, the Company identifies all material promised goods and services, which may include one or more of the following: a license to intellectual property and know-how, research and development services, and other transition support services. Promised goods or services are considered to be separate performance obligations if they are distinct. To determine the transaction price to be allocated to each performance obligation, in addition to any upfront payment, the Company estimates the amount of variable consideration at the outset of the contract either utilizing the expected value or most likely amount method, depending on the facts and circumstances relative to the contract. The Company constrains (reduces) the estimates of variable consideration such that it is probable that a significant reversal of previously recognized revenue, deferred revenue, or other amounts will not occur in future reporting periods. When determining if variable consideration should be constrained, management considers whether there are factors outside the Company's control that increase the likelihood of a significant reversal of previously recognized revenue and revenue-related amounts in future reporting periods. These estimates are re-assessed each reporting period as necessary depending on the facts and circumstances of each contract.

Once the estimated transaction price is established, amounts are allocated to identified performance obligations. The transaction price is generally allocated to each separate performance obligation on a relative standalone selling price basis. The Company must develop assumptions that require judgment to determine the standalone selling price (SSP) to account for these agreements. To determine the standalone selling price the Company's assumptions may include (i) assumptions regarding the probability of obtaining marketing approval for the drug candidate, (ii) estimates regarding the timing of and the expected costs to develop and commercialize the drug candidate, (iii) estimates of future cash flows from potential product sales with respect to the drug candidate and (iv) appropriate discount and tax rates. Standalone selling prices used to perform the initial allocation are not updated after contract inception. The Company does not include a financing component to its estimated transaction price at contract inception unless it estimates that certain performance obligations will not be satisfied within one year.

Upfront License Fees: If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from nonrefundable, upfront license fees based on the relative value prescribed to the license compared to the total value of the arrangement. The revenue is recognized when the license is transferred to the collaborator and the collaborator is able to use and benefit from the license. For licenses that are not distinct from other obligations identified in the arrangement, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time. If the combined performance obligation is satisfied over time, the Company applies an appropriate method of measuring progress for purposes of recognizing revenue from nonrefundable, upfront license fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

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

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

Common Stock Warrant Liability

The Company's outstanding common stock warrants issued in connection with certain equity and debt financings that occurred in 2013 through 2015 are classified as liabilities in the accompanying condensed consolidated balance sheets because of certain contractual terms that preclude equity classification. The Company estimates the fair value of common stock warrants at each reporting period until the earlier of the exercise of the warrants, at which time the liability will be revalued and reclassified to stockholders' equity, or expiration of the warrants, at which time any remaining liability will be settled and credited to other (expense) income, net. The determination of fair value of these common stock warrants requires 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. 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 other (expense) income, net, which could be material to the Company's results of operations.

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 stock options with time-based vesting 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 interest 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 is subject to remeasurement as the underlying equity instruments vest and is recognized as an expense over the period during which services are received.

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 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 of such securities are dilutive to net loss per share for the period, adjustments to 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 stock options, incentive awards and warrants outstanding at the end of each period were excluded from the calculation of diluted net loss per share because their effects were antidilutive. The Company's computation of basic and diluted net loss per share is as follows (in thousands, except share and per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Numerator:				
Net loss allocated to common stock-basic	$ (17,531)	$ (8,929)	$ (34,536)	$ (14,280)
Adjustments for revaluation of warrants	(198)	-	-	-
Net loss allocated to common stock-diluted	$ (17,729)	$ (8,929)	$ (34,536)	$ (14,280)
Denominator:				
Weighted average number of common stock shares outstanding - basic	58,833,647	28,752,451	56,307,236	27,687,110
Dilutive Securities:				
Common stock warrants	72,251	-	-	-
Weighted average number of common stock shares outstanding - diluted	58,905,898	28,752,451	56,307,236	27,687,110
Net loss per share - basic:	$ (0.30)	$ (0.31)	$ (0.61)	$ (0.52)
Net loss per share - diluted:	$ (0.30)	$ (0.31)	$ (0.61)	$ (0.52)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Warrants for common stock	729	1,667	729	1,667
Common stock options	5,074	3,803	5,074	3,803
Performance-based stock options	205	327	205	327
Incentive awards	130	239	130	239
	6,138	6,036	6,138	6,036

Recently Adopted Accounting Pronouncements

Accounting Standards Update 2014-09

On January 1, 2018, we adopted ASU No. 2014-09, *Revenue from Contracts with Customers* (Accounting Standards Codification Topic 606) (ASC 606) using the modified retrospective method applied to those contracts which were not completed as of January 1, 2018. The Company also elected to use the practical expedient that allows an entity to expense the incremental cost of obtaining a contract as an expense when incurred if the amortization period of the asset that an entity otherwise would have recognized is less than one year. Results for the three and six months ended June 30, 2018 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported in accordance with historic accounting under previous revenue recognition guidance. As of the adoption date, the Company had only one contract with a customer, Kowa Pharmaceuticals America, Inc. ("Kowa"), that had not been completed. Based on the Company's review, the Company concluded there was no significant change in applying ASC 606 to the contract with Kowa and no amounts have been recognized within "accumulated deficit" in the condensed consolidated balance sheet related to the adoption of the new standard.

Accounting Standards Update 2017-09

In May 2017, the Financial Accounting Standards Board (FASB) issued ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718) - Scope of Modification Accounting* (ASU 2017- 09). The amendments included in this update provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The amendments in this update will be applied prospectively to an award modified on or after the adoption date. The amendments in ASU 2017-09 became effective for the Company on January 1, 2018 and the adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.

Accounting Standards Update 2016-15

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230: Classification of Certain Cash Receipts and Cash Payments)* (ASU 2016-15). This guidance addresses specific cash flow issues with the objective of reducing the diversity in practice for the treatment of these issues. The areas identified include: debt prepayment or debt extinguishment costs; settlement of zero-coupon debt instruments; contingent consideration payments made after a business combination; proceeds from the settlement of insurance claims; proceeds from the settlement of corporate-owned life insurance policies; distributions received from equity method investees; beneficial interests in securitization transactions; and application of the predominance principle with respect to separately identifiable cash flows. The Company adopted ASU 2016-15 effective January 1, 2018. The adoption of this accounting standards update did not have a material impact on the Company's condensed consolidated financial statements.

Staff Accounting Bulletin No. 118

On December 22, 2017, the U.S. federal government enacted the Tax Cuts and Jobs Act ("the Act"). The Tax Act contains, among other things, significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21% for tax years beginning after December 31, 2017, limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, implementing a territorial tax system, and requiring a mandatory one-time tax on U.S. owned undistributed foreign earnings and profits known as the transition tax. In December 2017, SEC staff issued Staff Accounting Bulletin No. 118, *Income Tax Accounting Implications of the Tax Cuts and Jobs Act* ("SAB 118") to address the accounting implications of recently enacted U.S. federal tax reform. SAB 118 allows companies to record provisional amounts during a measurement period not to extend beyond one year of the enactment date to address ongoing guidance and tax interpretations that are expected over the next 12 months. The Company has adopted SAB 118 and currently considers its accounting of the impact of U.S. federal tax reform to be incomplete but continues to monitor and evaluate new guidance and interpretations and to evaluate their potential impact, if any, on the Company's existing deferred tax assets. The Company expects to complete the remainder of its monitoring and assessment analysis within the measurement period in accordance with SAB 118. Adjustments, if any, are not expected to impact the statement of operations and comprehensive loss due to the full valuation allowance on the Company's deferred tax assets.

Recently Issued Accounting Pronouncements

Accounting Standards Update 2018-07

In June 2018, the FASB issued ASU 2018-07, *Compensation – Stock Compensation* (Topic 718). This update is intended to simplify the accounting for share-based payments to non-employees by aligning it with the accountancy 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 will be substantially aligned. This standard will be effective for financial statements issued by public companies for the annual and interim periods beginning after December 15, 2018. Early adoption of the standard is permitted. The standard will be applied in a retrospective approach for each period presented. Management currently does not plan to early adopt this guidance and is evaluating the potential impact of this guidance on the consolidated financial statements as well as transition methods.

Accounting Standards Update 2016-02

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842).* The new standard requires the recognition of assets and liabilities arising from lease transactions on the balance sheet and the disclosure of key information about leasing arrangements. Accordingly, the lessee will recognize a lease asset for its right to use the underlying asset and a lease liability for the corresponding lease obligation. Both the asset and the liability will initially be measured at the present value of the future minimum lease payments over the lease term. Subsequent measurement, including the presentation of expenses and cash flows, will depend on the classification of the lease as either a finance or an operating lease. Initial costs directly attributable to negotiating and arranging the lease will be included in the asset. Lessees will also be required to provide additional qualitative and quantitative disclosures regarding the amount, timing and uncertainty of cash flows arising from leases. The new standard is effective for fiscal years beginning after December 15, 2018, and interim periods therein. Early adoption is permitted. As currently issued, entities are required to use a modified retrospective approach for leases that exist at or are entered into after the beginning of the earliest comparative period in the financial statements. There are additional optional practical expedients that an entity may elect to apply. In January 2018, the FASB issued an exposure draft of the proposed ASU, *Leases (Topic 842): Targeted Improvements*. The proposed ASU provides an alternative transition method of adoption, permitting the recognition of a cumulative-effect adjustment to retained earnings on the date of adoption. Management intends to adopt the standard on the effective date but has not yet selected a transition method. Management is in the process of inventorying and scoping the Company's population of leased assets in order to assess the impact of Topic 842. Topic 842 is expected to impact the Company's condensed consolidated financial statements as the Company has certain operating lease arrangements for which it is the lessee. Management is currently evaluating the impact adoption of Topic 842 will have on the Company's financial position and results of operations but management anticipates the recognition of additional assets and corresponding liabilities on the Company's condensed consolidated balance sheet related to leases.

Accounting Standards Update 2017-11

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share* (Topic 260); *Distinguishing Liabilities from Equity* (Topic 480); *Derivatives and Hedging* (Topic 815) (ASU 2017-11): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Non-controlling Interests with a Scope Exception. The ASU allows companies to exclude a down round feature when determining whether a financial instrument (or embedded conversion feature) is considered indexed to the entity's own stock. As a result, financial instruments (or embedded conversion features) with down round features may no longer be required to be accounted for and classified as liabilities. A company will recognize the value of a down round feature only when it is triggered and the strike price has been adjusted downward. For equity-linked freestanding financial instruments, such as warrants, an entity will treat the value of the effect of the down round, when triggered, as a dividend and a reduction of income available to common shareholders in computing basic earnings per share. For convertible instruments with embedded conversion features containing down round provisions, entities will recognize the value of the down round as a beneficial conversion discount to be amortized to earnings. The guidance in ASU 2017-11is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted, and the guidance is to be applied using a full or modified retrospective approach. We are currently evaluating the impact of the revised guidance on its condensed consolidated financial statements.

3. Certain Balance Sheet Items

The following table shows certain balance sheet items (in thousands):

	June 30, 2018	December 31, 2017
	(unaudited)	
Accrued compensation	$ 1,296	$ 2,416
Accrued professional fees	539	288
Other	236	124
Total other accrued liabilities	$ 2,071	$ 2,828

4. Collaboration and License Agreements

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 will have 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). At Kowa's option, the Company may also facilitate the placement of arhalofenate product manufacturing orders under the terms of the Company's existing contract manufacturing agreements. In addition, the Company will complete specified in-process stability testing and non-clinical development services and will participate on a Joint Advisory Committee (JAC). Finally, the Company will transfer to Kowa certain arhalofenate product on hand.

Under the license agreement, Kowa agreed to pay the Company a non-refundable upfront payment of $5.0 million upon contract execution. Kowa also agreed to pay the Company $5.0 million upon initiation of a study evaluating the pharmacokinetics of arhalofenate in subjects with renal impairment, which occurred during the quarter ended December 31, 2017 and was received in January 2018. An additional milestone payment of $5.0 million is due on initiation of a Phase 3 study of arhalofenate, and up to $190.0 million based upon the achievement of other specific development and sales milestones. Finally, the Company will receive tiered, double digit royalties on any product sales and a percentage of any sublicensing revenue earned by Kowa.

Kowa may terminate the agreement by giving a 45-day notice to the Company three months after the effective date of the agreement and any time thereafter with a 90 day notice. Unless terminated early, the agreement has a term that ends on the later of the (i) expiration of the last to exist valid claim covering the manufacture, use and sale of arhalofenate in the United States and (ii) the 10th anniversary of the first commercial sale. The license agreement may be terminated for cause by either party based on uncured material breach by the other party, bankruptcy of the other party or for safety reasons. Upon early termination, the license and know how all revert back to the Company.

The Company concluded that Kowa is a customer, and the contract is not subject to accounting literature on collaborative arrangements. This is because the Company granted to Kowa a license to its intellectual property and provided drug product and research and pre-clinical development services, all of which are outputs of the Company's ongoing activities, in exchange for consideration. The Company identified the following three material promises under the license agreement: 1) the transfer of a license to intellectual property, inclusive of the related technology know-how conveyance and contract manufacturing rights and privileges ("license and know-how"); 2) the performance of specific ongoing research and non-clinical development services, and 3) the delivery of existing on hand arhalofenate clinical product. The Company's participation on the JAC is not a performance obligation as the Company's participation in the JAC is not required and is primarily for the Company's benefit to obtain updates on the progress of Kowa's activities. The Company provided to Kowa standard indemnification and protection of licensed intellectual property, which is part of assurance that the license meets the contract's specifications and is not an obligation to provide goods or services.

The Company concluded that the license and know-how, the research and development services, and delivery of arhalofenate product were separate performance obligations since each was identified as a material promise that was by itself distinct. The Company concluded that Kowa can benefit from the license and know-how on its own by developing and commercializing arhalofenate using its own resources, and has the ability to sublicense and manufacture arhalofenate. The research and non-clinical development services promised will not significantly change the intellectual property underlying the license. Further, the Company believes that Kowa has research and development expertise with compounds similar to those licensed under the agreement. The research and development services and arhalofenate product are not integrated or dependent upon each other and are provided by the Company separately from each other. The licensed intellectual property was considered to be functional as it has significant standalone functionality, and grants Kowa the right to use the Company's intellectual property as it exists on the effective date of the license. Accordingly, license revenue was recognized upon the substantial completion of the license technology transfer during 2017. The research and non-clinical development services are transferred as the services are performed, with cost used as the measure of

progress. The arhalofenate product was transferred when Kowa assumed title and control of the inventory stored at the Company's contract manufacturer upon entering into a direct contract with such manufacturer in the fourth quarter of 2017.

To allocate transaction price among the three performance obligations, the Company estimated their standalone selling price (SSP). For the license and know-how, the SSP was estimated using the income approach based on assumptions regarding Kowa's future revenues from the licensed intellectual property, projected costs of research and development, manufacturing and commercialization expenses, as well as the discount rate, the development timeline, and probabilities of technical and regulatory success. To estimate SSP of research and non-clinical development services and arhalofenate product on hand, the Company used a cost-plus margin approach. The Company believes that a change in the assumptions used to determine its best estimate of selling price for the performance obligations would not have a significant effect on the allocation of consideration received to the performance obligations.

As of January 1, 2018, the transaction price was limited to $10.0 million, consisting of a $5.0 million upfront fee due upon contract initiation and a $5.0 million development milestone payment triggered when Kowa initiated a study evaluating the pharmacokinetics of arhalofenate in subjects with renal impairment. Of these amounts, the Company allocated $9.5 million to the license; $0.4 million to the arhalofenate product; and $0.1 million to the research and pre-clinical development services. As of January 1, 2018, all these performance obligations had been completed and the associated revenue had been recognized.

The variable consideration related to the remaining development milestone payments has not been included in the transaction price as these milestones were fully constrained at June 30, 2018. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and Kowa's efforts. Any variable consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to Kowa. The Company re-evaluates the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

The Company expensed the incremental costs of obtaining the Kowa contract prior to December 31, 2017, as substantially all costs related to the performance obligations completed by that date.

Revenue recognized during the three and six months ended June 30, 2017 was determined in accordance with the accounting rules applicable prior to the adoption of ASC 606 on January 1, 2018. There was no difference in the revenue recognized under ASC 606 or legacy GAAP for the three and six months ended June 30, 2018.

There were no contract assets or deferred revenues (contract liabilities) recorded during the six months ended June 30, 2018. Accounts receivable from the Kowa contract consisted of the following (in thousands):

	June 30, 2018	December 31, 2017
Accounts receivable	$ -	$ 5,000

As of June 30, 2018, there were no amounts included in the transaction price and allocated to goods and services not yet provided.

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 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.

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. No amounts were incurred or accrued for this agreement as of and for the three and six months ended June 30, 2018 and 2017.

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. No development payments were made or became due as of and for the three and six months ended June 30, 2018 and 2017 and no royalties have been paid to date. In December 2016, the agreement was amended by the parties to change the timing of a specified development milestone.

5. Facility Loans

On September 30, 2013, the Company entered into a facility loan agreement with Silicon Valley Bank and Oxford Finance LLC (referred to herein as the lenders) whereby $5.0 million was drawn as part of the Company's September 2013 financing, referred to herein as the 2013 Term Loan Facility. In connection with the 2013 Term Loan Facility, the Company also issued warrants exercisable for a total of 121,739 shares of the Company's common stock to the lenders at an exercise price of $5.00 per share with a term of seven years.

On August 7, 2015, the Company entered into a Loan and Security Agreement, pursuant to which the Company refinanced its existing 2013 Term Loan Facility with Oxford Finance LLC and Silicon Valley Bank, and borrowed an aggregate of $10.0 million, of which $5.9 million was outstanding on December 31, 2017. In connection with this 2015 Term Loan Facility, the Company issued warrants exercisable for a total of 114,436 shares of its common stock to the lenders at an exercise price of $2.84 per share, and with a term of ten years.

On June 4, 2018, the Company 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, the Company recorded a $0.4 million loss on early of extinguishment of this debt. As of June 30, 2018, the Company had no further obligations under the 2015 Term Loan Facility.

6. Commitments and Contingencies

The Company leases 8,894 square feet of office space in Newark, California pursuant to a lease which commenced January 16, 2014 and expires on January 15, 2019.

On April 16, 2018, the Company entered into an amended lease to extend the term of its original lease to January 15, 2024 and relocate and expand its office space within the same office park in Newark, California. The Company has an option to further extend the term of the amended lease for an additional five years, which would commence upon the expiration of the lease term. The lease agreement includes an escalation clause for increased rent and a renewal provision allowing the Company to extend this lease for an additional five years by giving the landlord written notice of the election to exercise the option prior to the original expiration of the lease term. The lease provides for monthly base rent amounts escalating over the term of the lease and the lessor also agreed to fund and complete the construction of certain tenant improvements. The Company estimated the value of this tenant improvement allowance at $2.1 million and recorded it as deferred rent liability and other current assets on the balance sheet at June 30, 2018. It will be reclassified to leasehold improvements within property and equipment when realized, and depreciated over the remaining lease term.

Rent expense was $0.1 million for each of the three months ended June 30, 2018 and 2017, and $0.3 million for each of the six months ended June 30, 2018 and 2017.

Future minimum lease payments are as follows (in thousands):

	Lease Payments
2018 (from July to December)	$ 114
2019	627
2020	645
2021	664
2022 and beyond	1,390
Total future minimum payments	$ 3,440

7. Stockholders' Equity

As of June 30, 2018, and December 31, 2017, the Company had reserved shares of authorized but unissued common stock as follows:

	June 30, 2018	December 31, 2017
	(unaudited)	
Common stock warrants	729,483	1,460,955
Equity incentive plans	7,013,933	4,021,983
Total reserved shares of common stock	7,743,416	5,482,938

On February 1, 2018, pursuant to a shelf registration statement on Form S-3, the Company completed the issuance of 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 in connection with the February 2018 public offering were approximately $135.5 million after deducting underwriting discounts, commissions and other offering expenses.

8. Stock Plans and Stock-Based Compensation

Stock Plans

On January 1, 2018, the share reserve of the Company's 2013 Equity Incentive Plan (2013 Plan), automatically increased by 2,220,439 shares. During the six months ended June 30, 2018, the Company granted options to purchase 1,725,272 shares of its common stock to its employees, directors and a consultant. On June 5, 2018, the Company's stockholders approved a 1,500,000 share increase in the number of shares to be reserved under the 2013 Plan. As of June 30, 2018, there were 1,605,403 shares available for grant under the 2013 Plan.

Stock-Based Compensation Expense

Stock-based compensation expense recorded was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(unaudited)		(unaudited)	
Research and development	$ 655	$ 268	$ 1,304	$ 628
General and administrative	1,096	1,572	2,243	2,490
Total	$ 1,751	$ 1,840	$ 3,547	$ 3,118

9. Related-Party Transactions

The Company paid a former member of its Board of Directors, who is also a member of its Scientific and Clinical Advisory Board, a total of $15,000 for the three months and $30,000 of the six months ended June 30, 2018 and 2017, in monthly cash retainers.

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

Operating results for the three and six months ended June 30, 2018, 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. We usually use words such as "may," "will," "could," "expect," "plan," "anticipate," "believe," "estimate," "intend," or the negative of these terms or similar expressions to identify these 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 and our collaborators' product development programs, including clinical testing, and the timing of results thereof; our corporate collaborations and revenues that may be received from our collaborations and the timing of those potential payments; 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, and under the heading "Risk Factors" in Item 1A of our Annual Report on Form 10-K, filed with the SEC on March 15, 2018. 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 PPARδ, a nuclear receptor that regulates genes involved in bile acid/sterol, lipid and glucose metabolism and inflammation. We are currently developing seladelpar for the treatment of primary biliary cholangitis (PBC), an autoimmune disease that causes progressive destruction of the bile ducts in the liver. We are also developing seladelpar for the treatment of 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.

Data from two Phase 2 studies of seladelpar in patients with PBC have established seladelpar's anti-cholestatic and anti-inflammatory effects. In April 2018, we announced updated positive interim results from an ongoing low-dose Phase 2 study of seladelpar in patients with PBC. In the first part of the study, patients with an inadequate response to ursodeoxycholic acid (UDCA), as characterized by a persistent elevation in alkaline phosphatase (AP), or who were intolerant to UDCA, received either 2 mg, 5 mg or 10 mg of seladelpar once-daily through 12 weeks. At baseline, mean AP was 358, 333, and 262 U/L in the 2 mg, 5 mg, and 10 mg groups, respectively. At 12 weeks, changes in AP were -21%, -33%, and -45% in the 2 mg (N=6), 5 mg (N=25), and 10 mg (N=22) groups, respectively. After 12 weeks, dose titration was permitted for patients whose AP remained above normal and at a level where additional AP lowering had the potential to reduce the risk of disease progression. At 26 weeks, decreases in AP were similar across regimens at -45%, -43%, and -43% in the 5 mg (N=13), 5 to 10 mg titration (N=6) and 10 mg (N=19) groups, respectively. AP is a recognized biomarker of cholestasis. Reaching an AP level of less than 1.67 times the upper limit of normal (ULN) after one year of treatment along with a decrease in AP of at least 15% from baseline are two key components in the composite endpoint used for regulatory approval; a third element in the composite endpoint is having normal levels of total bilirubin at one year. At 26 weeks, 69%, 67%, and 79% of patients in the 5 mg, 5 to 10 mg titration and 10 mg dose regimens, respectively, had an AP less than 1.67 times the upper limit of normal, with at least a 15% decrease in AP from baseline and normal bilirubin. Overall, 29% of patients had a normal AP at 26 weeks.

In addition to the reduction in AP, patients in both the 5 mg and 10 mg dose groups experienced decreases in other liver markers of cholestasis including gamma glutamyl transferase and total bilirubin. Seladelpar also improved metabolic and inflammatory markers with patients experiencing decreases in levels of low-density lipoprotein-C and high sensitivity C-reactive protein.

At 12 weeks, median transaminase changes were -9%, -28%, and -35% in the 2 mg, 5 mg, and 10 mg groups, respectively and decreases were maintained at 26 weeks in the 5 mg and 10 mg groups (≥ -40%). These decreases further support seladelpar's anti-inflammatory activity.

Many PBC patients suffer from pruritus, or chronic itching, which can significantly impact their quality of life. Consistent with prior studies, seladelpar was not associated with drug-induced pruritus. Baseline median pruritus was measured by the visual analog scale (VAS) on a scale of 0 to 100 mm and was 19 and 27 mm in patients initially assigned to 5 mg and 10 mg, respectively. Patients in the 10 mg group experienced consistent decreases during treatment (-24% at week 26) suggesting potential anti-pruritic activity. Seladelpar was generally safe and well tolerated, with no transaminase elevation safety signal. There were six serious adverse events with none of these deemed related to seladelpar.

In June 2018, we announced enrollment in the ongoing study was complete with a total of 109 patients. We expect to report another subset of data through 52-weeks of dosing in the second half of 2018. We intend to initiate a Phase 3 study in PBC in the second half of 2018.

In November 2016, the FDA granted orphan drug designation to seladelpar for the treatment of PBC, and in September 2017, the EMA's Committee for Orphan Medicinal Products (COMP) similarly granted orphan drug designation to seladelpar for the treatment of PBC. In October 2016, seladelpar received EMA PRIority MEdicines (PRIME) designation for the treatment of PBC.

We believe that seladelpar could also have utility in the treatment of NASH. Seladelpar was found to reverse NASH pathology, decrease fibrosis, inflammation, hepatic lipids and reverse insulin resistance in the *foz/foz* mouse, which is a diabetic obese model of NASH. In April 2018, we initiated screening a double-blind, randomized, placebo-controlled 52-week Phase 2b clinical study evaluating the safety and efficacy of 10, 20 and 50 mg of seladelpar versus placebo in patients with NASH. The primary objectives of the study are to evaluate the effect of seladelpar on hepatic fat, as assessed by magnetic resonance imaging-proton density fat fraction (MRI-PDFF) at week 12 and to evaluate the safety and tolerability of seladelpar in subjects with NASH. The study is intended to enroll a total of 175 patients with liver biopsy-proven NASH in a 2:2:2:1 randomization between 10, 20 and 50 mg of seladelpar and placebo. Among various secondary objectives includes evaluation of histological improvement in NASH and fibrosis as assessed by comparing liver biopsy samples taken at baseline and 52 weeks.

Our second product candidate, arhalofenate, is a dual-acting anti-inflammatory and uric acid lowering agent being developed for the treatment of gout. In 2016, we entered into an exclusive licensing agreement granting Kowa Pharmaceuticals America, Inc. the rights to develop and commercialize arhalofenate in the United States (including all possessions and territories). Under the terms of the agreement with Kowa, we received an up-front payment of $5.0 million, and a milestone payment of $5.0 million for the initiation of a study evaluating the pharmacokinetics of arhalofenate in subjects with renal impairment. We are entitled to receive an additional milestone payment of $5.0 million on the initiation of a Phase 3 study and up to an additional $190.0 million in payments based upon the achievement of specific development and sales milestones. We are also eligible to receive tiered, double digit royalties on future sales of arhalofenate products. Kowa will be responsible for all development and commercialization costs. We retain full development and commercialization rights for the rest of the world and intend to partner arhalofenate in geographies outside the United States and its possessions and territories.

Equity Financings

On February 7, 2017, pursuant to our shelf registration statement on Form S-3, we completed the issuance of 5,181,348 shares of our common stock at $1.93 per share, which we refer to as our February 2017 public offering. Net proceeds to us in connection with the February 2017 public offering were approximately $9.2 million after deducting underwriting discounts, commissions and other offering expenses.

On May 11, 2017 we filed a $100 million shelf registration statement on Form S-3, which was declared effective on June 29, 2017, and our prior shelf registration statement was deemed terminated. This new shelf registration statement included an at-the-market facility (New ATM) to sell up to $25 million of common stock under the new registration statement. We terminated the New ATM in July 2017.

On July 24, 2017, pursuant to the $100 million shelf registration statement on Form S-3, we completed the issuance of 14,950,000 shares of our common stock at $6.50 per share, which we refer to as our July 2017 public offering. Net proceeds to us in connection with the July 2017 public offering were approximately $91.1 million after deducting underwriting discounts, commissions and other offering expenses.

On December 29, 2017 we filed a new $200 million shelf registration statement on Form S-3, which was declared effective on January 19, 2018, and our prior shelf registration statement was deemed terminated.

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 to us in connection with the February 2018 public offering were approximately $135.5 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 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 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 and review our estimates on an ongoing basis. Actual results may materially differ from these estimates under different assumptions or conditions. For further information on our significant accounting policies, except for revenue recognition which is discussed further below, refer to our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the SEC on March 15, 2018.

Revenue Recognition

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

Effective January 1, 2018, we adopted Accounting Standards Codification, or ASC Topic 606, *Revenue from Contracts with Customers* (ASC 606) using the modified retrospective method, for all contracts that had not been completed as of that date. As of the adoption date, we had entered into one out-licensing agreement that was within the scope of ASC 606, under which we have licensed certain of our product candidate rights to a third party. The terms of this arrangement included a non-refundable, up-front license fee, development and commercial milestone payments, and royalties on net sales of licensed products. Any revenues resulting from these payments are collectively classified as collaboration revenue, except for royalties on net sales of licensed products, which are classified as royalty revenues.

At the inception of an arrangement, we evaluate if a counterparty to a contract is a customer, if the arrangement is within the scope of revenue from contracts with customers guidance, and the term of the contract. We recognize revenue when the customer obtains control of promised goods or services in a contract for an amount that reflects the consideration we expect to receive in exchange for those goods or services. For contracts with customers, we apply the following five-step model in order to determine this amount: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including any constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. As part of the accounting for contracts with customers, we must develop assumptions that require judgment to determine the standalone selling price of each performance obligation identified in the contract. We then allocate the total transaction price to each performance obligation based on the estimated standalone selling prices of each performance obligation. We recognize the amount of the transaction price as revenue that is allocated to the respective performance obligation when the performance obligation is satisfied or as it is satisfied. Generally, our performance obligations are transferred to customers at a point in time, typically upon delivery.

Upfront License Fees: If a license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from nonrefundable, upfront license fees based on the relative value prescribed to the license compared to the total value of the arrangement. The revenue is recognized when the license is transferred to the collaborator and the collaborator is able to use and benefit from the license. For licenses that are not distinct from other obligations identified in the arrangement, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time. If the combined performance obligation is satisfied over time, we apply an appropriate method of measuring progress for purposes of recognizing revenue from nonrefundable, upfront license fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Development and Regulatory Milestone Payments: Depending on facts and circumstances, we may conclude that it is appropriate to include a milestone payment in the estimated transaction price using the most likely amount method or that it is appropriate to fully constrain the milestone. A milestone payment is included in the transaction price in the reporting period that we conclude that it is probable that recording revenue in the period will not result in a significant reversal in amounts recognized in future periods. We may record revenues from certain milestones in a reporting period before the milestone is achieved if we conclude that achievement of the milestone is probable and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods. We record a corresponding contract asset when this conclusion is reached. Milestone payments that have not been included in the transaction price to date are fully constrained. These milestones remain fully constrained until we conclude that achievement of the milestone is probable and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods. We re-evaluate the probability of achievement of such development milestones and any related constraint each reporting period. We adjust our estimate of the overall transaction price, including the amount of collaborative revenue that was recorded, if necessary.

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

We receive payments from our customers based on billing schedules established in each contract. Up-front payments and fees are recorded as deferred revenue upon receipt or when due until we perform our obligations under these arrangements. Amounts are recorded as accounts receivable when our right to consideration is unconditional. We do not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

As of the adoption date of ASC 606, we had only one contract with a customer, Kowa Pharmaceuticals America, Inc. (Kowa), that had not been completed. Based on our review, we concluded there was no significant change in applying ASC 606 to the contract with Kowa and no amounts have been recognized within "accumulated deficit" in the condensed consolidated balance sheet related to the adoption of the new standard.

Results of Operations

General

To date, we have not generated any income from operations. As of June 30, 2018, we had an accumulated deficit of $485.1 million, primarily as a result of expenditures for research and development and general and administrative expenses from inception to that date. While we have generated revenue from our license arrangement with Kowa and may in the future generate revenue from a variety of other sources, including additional milestone payments from Kowa and license fees and milestone payments in connection with other strategic partnerships, arhalofenate and seladelpar are 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 six months ended June 30, 2018 and 2017 are presented below:

	Three Months Ended June 30,			Six Months Ended June 30,		
	2018	2017	Variance	2018	2017	Variance
($ in thousands)						
Collaboration revenue	$ -	$ -	$ -	$ -	$ 4,793	$ (4,793)
Operating expenses:						
Research and development	14,397	4,044	10,353	23,874	8,085	15,789
General and administrative	3,574	3,582	(8)	6,947	7,283	(336)
Loss from operations	(17,971)	(7,626)	(10,345)	(30,821)	(10,575)	(20,246)
Interest income (expense), net	933	(239)	1,172	1,433	(507)	1,940
Loss on extinguishment of debt	(407)	-	(407)	(407)	-	(407)
Other expense, net	(86)	(1,064)	978	(4,741)	(3,198)	(1,543)
Net loss	$ (17,531)	$ (8,929)	$ (8,602)	$ (34,536)	$ (14,280)	$ (20,256)

Collaboration Revenue

No collaboration revenue was recognized for the three and six months ended June 30, 2018. Collaboration revenue for the three and six months ended June 30, 2017 was none and $4.8 million, respectively. We recognized collaboration revenue in the six months ended June 30, 2017 following the delivery of the license and knowhow deliverable identified in our Kowa license and collaboration agreement.

Research & Development Expenses

Conducting research and development is central to our business model. For the three months ended June 30, 2018 and 2017, research and development expenses were $14.4 million and 4.0 million, respectively. For the six months ended June 30, 2018 and 2017, research and development expenses were $23.9 million and $8.1 million, respectively. Research and development expenses are detailed in the table below:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
($ in thousands)	(unaudited)		(unaudited)	
Seladelpar PBC clinical studies	$ 5,191	$ 1,469	$ 8,854	$ 3,050
Seladelpar NASH clinical studies	3,645	-	4,427	-
Seladelpar drug manufacturing & development	1,636	805	3,438	1,476
Seledelpar other studies	333	234	503	328
Non-seladelpar studies	27	83	54	159
Total Project Costs	10,832	2,591	17,276	5,013
Internal research and development costs	3,565	1,453	6,598	3,072
Total Research and Development	$ 14,397	$ 4,044	$ 23,874	$ 8,085

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.

Total project costs increased by $8.2 million to $10.8 million from $2.6 million for the three months ended June 30, 2018 and 2017, respectively. Project costs for the three months ended June 30, 2018 and 2017 consisted primarily of seladelpar-related clinical trial expenses. Specifically, clinical project costs increased in 2018 primarily due to the expansion and extension of our PBC Phase 2 clinical trial, the initiation of start-up activities related to our upcoming PBC Phase 3 clinical trial, the commencement of our NASH Phase 2b clinical trial in April 2018, and the execution of other NDA-enabling studies. In addition, project costs increased due to manufacturing of seladelpar to support ongoing and planned clinical trials and other development activities. Internal research and development costs increased by $2.1 million for the three months ended June 30, 2018, as compared to June 30, 2017, primarily due to higher employee compensation related expenses as we hired additional clinical, scientific and regulatory personnel to support of our expanding clinical development activities.

Total project costs increased by $12.3 million to $17.3 million from $5.0 million for the six months ended June 30, 2018 and 2017, respectively. Project costs for the six months ended June 30, 2018 and 2017 consisted primarily of seladelpar-related clinical trial expenses. Specifically, clinical project costs increased in 2018 primarily due to the expansion and extension of our PBC Phase 2 clinical trial, the initiation of start-up activities related to our upcoming PBC Phase 3 clinical trial, the commencement of our NASH Phase 2b clinical trial in April 2018, and the execution of other NDA-enabling studies. In addition, project costs increased due to manufacturing of seladelpar to support ongoing and planned clinical trials and other development activities. Internal research and development costs increased by $3.5 million for the six months ended June 30, 2018, as compared to June 30, 2017, primarily due to higher employee compensation related expenses as we hired additional clinical, scientific and regulatory personnel to support of our expanding clinical development activities.

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 example, as a result of the favorable interim PBC clinical trial results we announced in July 2017, we expanded and extended our ongoing PBC Phase 2 study and we are preparing to initiate a PBC Phase 3 study of seladelpar in the second half of 2018 along with other NDA-enabling studies. Furthermore, we commenced screening of a Phase 2 clinical study in NASH in April of 2018. Accordingly, we expect to incur substantial costs to prepare for and conduct these clinical trials and other seladelpar-related development activities.

General and Administrative Expenses

General and administrative expenses consist principally of personnel-related costs, professional fees for legal, consulting, audit services, and other general operating expenses not otherwise included in research and development. General and administrative expenses remained flat at $3.6 million for the three months ended June 30, 2018 and 2017. For the three months ended June 30, 2018, higher consulting expenses were offset by lower stock-based compensation and professional fees when compared to the same period in 2017. General and administrative expenses decreased by $0.4 million to $6.9 million from $7.3 million for the six months ended June 30, 2018 and 2017, respectively, primarily due to lower severance expenses, stock-based compensation and professional fees, partially offset by higher consulting expenses.

Interest Income (Expense), Net

Interest income (expense), net consists primarily of interest income from our marketable securities offset in part by interest expense related to our loan facility. Interest income (expense), net increased by $1.1 million to $0.9 million from $(0.2) million for the three months ended June 30, 2018 and 2017, respectively, primarily due to higher interest income earned from our marketable securities in the second quarter of 2018. Interest income (expense), net increased by $1.9 million to $1.4 million from $(0.5) million for the six months ended June 30, 2018 and 2017, respectively, primarily due to higher interest income earned from our marketable securities in the first half of 2018. Interest income rose because we invested a significant portion of the proceeds received from our July 2017 and February 2018 public offerings in marketable securities.

Loss on Extinguishment of Debt

In connection with the early payoff our of our term loan facility in June 2018, we recognized a $0.4 million loss on the extinguishment of debt.

Other Expense, Net

Other expense, net primarily includes losses resulting from the remeasurement of our investor and lender warrant liabilities at fair value. We use an option pricing model to revalue our warrant liabilities at each reporting date. A decline in the value of our warrant liabilities results in the recognition of a remeasurement gain. Conversely, an increase in the value of our warrant liabilities results in the recognition of a remeasurement loss. During the third quarter of 2017, we changed our valuation technique and began to revalue our warrants using a Black-Scholes option pricing model. Historically, we used a binomial option pricing model to revalue the warrant liabilities.

Other expense, net reflected a loss of $0.1 million and $1.1 million for the three months, and $4.7 million and $3.2 million for the six months ended June 30, 2018, and 2017, respectively, in each case due to the remeasurement of our warrant liabilities at fair value. The losses recognized were primarily due to an increase in the price of our common stock from $9.20 at December 31, 2017 to $12.99 at March 31, 2018 to $13.42 at June 30, 2018, and from $1.73 at December 31, 2016 to $4.30 at March 31, 2017 to $5.76 at June 30, 2017.

Liquidity and Capital Resources

Due to our significant research and development expenditures, we have generated significant operating losses since our inception. We have financed our operations primarily through the sale of equity securities, licensing fees, issuance of debt and collaborations with third parties. At June 30, 2018, we had cash, cash equivalents and marketable securities of $212.1 million, compared to $97.2 million at December 31, 2017. 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. For example, as a result of the favorable interim PBC clinical trial results we announced in July 2017, we expanded and extended our ongoing PBC Phase 2 study and we are preparing to initiate a PBC Phase 3 study of seladelpar in the second half of 2018 along with other NDA-enabling studies. Furthermore, we commenced screening of a Phase 2 clinical study in NASH in April of 2018. Accordingly, we expect to incur substantial costs to prepare for and conduct these clinical trials and other seladelpar-related development activities. 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. As of June 30, 2018, we had no further obligations under this agreement.

Cash Flows

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

	Six Months Ended June 30,	
	2018	2017
Net cash used in operating activities	$ (19,264)	$ (8,094)
Net cash used in by investing activities	(92,489)	(722)
Net cash provided by financing activities	133,425	7,830
Net increase (decrease) in cash and cash equivalents	$ 21,672	$ (986)

Operating Activities: Net cash used in operating activities for the six months ended June 30, 2018 was $19.3 million primarily due to a net loss of $34.5 million resulting from our expanding drug development activities, offset in part by the receipt of a $5.0 million milestone payment from Kowa, a $4.7 million non-cash loss recorded to revalue our warrant liability, $3.5 million of stock-based compensation and other changes in operating assets and liabilities.

Investing Activities: Net cash used in investing activities was $92.5 million for the six months ended June 30, 2018, as a result of net purchases of marketable securities, as we sought to invest a portion of the proceeds from our February 2018 public offering.

Financing Activities: Net cash provided by financing activities for the six months ended June 30, 2018 was $133.4 million, due to net proceeds of $135.5 million received from the February 2018 public offering, net proceeds of $3.5 million received from issuance of common stock pursuant to our equity award plans, and proceeds of $1.0 million received from warrant exercises, offset by $6.7 million due to the full repayment of our facility loan.

Contractual Obligations and Commitments

Our aggregate contractual obligations as of June 30, 2018, were $3.4 million as compared to $7.2 million as of December 31, 2017. Contractual obligations decreased primarily because we paid off our term loan facility in full in June 2018. This repayment caused our contractual obligations under our term loan facility to decrease from $7.0 million as of December 31, 2017, to none as of June 30, 2018. Partially offsetting this decrease was an increase in operating lease obligations from $0.2 million to $3.4 million following the execution of our amended lease to extend the term of our original lease to January 15, 2024 and relocate and expand our office space.

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 $212.1 million as of June 30, 2018, compared to $97.2 million at December 31, 2017. As of June 30, 2018 and December 31, 2017, our cash, cash equivalents, and investments were held 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 June 30, 2018, or December 31, 2017. We actively monitor changes in interest rates.

Foreign Exchange

Our operations are primarily conducted 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 are denominated in the local currency. Transactional exposure arises when transactions occur in currencies other than the U.S. Dollar. Transactions denominated in foreign currencies are recorded 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 six months ended June 30, 2018 and 2017, 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

(a) *Evaluation of Disclosure Controls and Procedures.* Based on the evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), our principal executive officer and principal financial officer have concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective at the reasonable assurance level.

(b) *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 principal executive officer and principal financial officer 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.

(c) *Changes in Internal Controls.* There were no changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2018, 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

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 June 30, 2018, we had cash, cash equivalents and marketable securities of approximately $212.1 million. We believe that these funds will allow us to continue operation with 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 extent to which we receive the milestone payments and royalties under our licensing agreement with Kowa;
- the extent to which we are able to out-license arhalofenate outside of the United States;
- the need for additional or expanded clinical studies;
- the rate of progress and cost of our Chemistry, Manufacturing and Control development, registration and validation program;
- 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.

We are dependent on our partner, Kowa Pharmaceuticals America, Inc., for the successful development, regulatory approval and commercialization of arhalofenate in the United States.

In December 2016, we entered into an exclusive licensing agreement with Kowa Pharmaceuticals America, Inc., or Kowa, for the development and commercialization of arhalofenate for the treatment of gout in the United States (including all possessions and territories). The terms of our licensing agreement with Kowa provide them with exclusive authority over the development and commercialization plans for arhalofenate in the United States and the execution of those plans. We have no effective influence over those plans and are dependent on Kowa's decision making. In January 2018 we received a $5.0 million milestone payment from Kowa for the initiation of a study evaluating the pharmacokinetics of arhalofenate in subjects with renal impairment. Under the license agreement, Kowa has also agreed to pay an additional milestone payment of $5.0 million on the initiation of a Phase 3 study, and we are eligible to receive up to an additional $190.0 million in payments based upon the achievement of additional development and sales milestones. We are also eligible to receive tiered, double digit royalties on future sales of arhalofenate products.

We are dependent upon Kowa to develop arhalofenate further. Any significant changes to Kowa's business strategy and priorities, over which we have no control, could adversely affect Kowa's willingness or ability to complete their obligations under our licensing agreement and could result in harm to our business and operations. Subject to contractual diligence obligations, Kowa has complete control over and financial responsibility for arhalofenate's development program and regulatory strategy and execution, and we are not able to control the amount or timing of resources that Kowa will devote to the product. If Kowa does not diligently pursue the development or commercialization of arhalofenate, we will not receive any further payments under the licensing agreement and our ability to derive value from arhalofenate will be seriously harmed. Further, regardless of Kowa's efforts and expenditures for the further development of arhalofenate, the results of such additional clinical investigation may not provide positive results and may not result in a commercial product due to regulatory or other reasons similar to those described below with respect to seladelpar.

The current plan is to use arhalofenate in combination with febuxostat, a treatment for gout currently marketed by Takeda Pharmaceuticals. However, in November 2017, the FDA issued an alert noting that preliminary results from a safety clinical trial of febuxostat showed an increased risk of heart-related death with febuxostat compared to another gout medicine called allopurinol. The FDA recommended that health care professionals consider this safety information when deciding whether to prescribe or continue patients on febuxostat. It is not known whether this safety information and/or the FDA alert will have a significant impact on the continued use of febuxostat. Reduced use of febuxostat could have a significant negative affect on the development prospects of arhalofenate and could negatively impact the willingness or ability of Kowa to continue development of arhalofenate.

We do not intend to invest further in the development and commercialization of arhalofenate, and currently intend to out-license the rights to arhalofenate outside of the United States.

In December 2016, we entered into an exclusive licensing agreement with Kowa for the development and commercialization of arhalofenate in the United States (including all possessions and territories). We currently intend to out-license the development and commercialization of arhalofenate outside of the United States, and do not intend to invest further in the development and commercialization of arhalofenate. However, there is no guarantee that our efforts to out-license arhalofenate in countries outside of the United States will result in any licensing agreements or, if they do result in licensing agreements, that we will derive any value from those agreements. We expect the terms of those licensing agreements, if any, will provide the licensee with exclusive authority over the development and commercialization plans for arhalofenate in the jurisdiction(s) covered by the licensing agreement, and that we will have no influence over the actions of the licensees and will be dependent on their decision making. In the event that we are not able to enter into any further license agreements, or the licensees' do not, or are not able to, develop or commercialize arhalofenate in their respective jurisdictions, our ability to derive further value from arhalofenate will be seriously harmed.

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 future revenues from product sales depends heavily on our success in:

- the performance of Kowa under our licensing agreement, including whether development milestones and regulatory approvals regarding arhalofenate are achieved;
- our ability to out-license arhalofenate in jurisdictions outside of the United States;
- obtaining favorable 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 and 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. 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. For example, in December 2016 we entered into an agreement to license our right to develop and commercialize arhalofenate for the treatment of gout in the United States in exchange for consideration including (i) a $5.0 million upfront payment, (ii) a $5.0 million milestone payment for the initiation of a study evaluating the pharmacokinetics of arhalofenate in subjects with renal impairment, (iii) eligibility to receive an additional milestone payment of $5.0 million on the initiation of a Phase 3 study, as well as (iv) up to an additional $190.0 million in payments based upon the achievement of additional development and sales milestones and (v) tiered, double digit royalties on any product sales.

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 are currently an emerging growth company and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and will remain an emerging growth company until December 31, 2018. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. However, we have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and, therefore, are subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

For as long as we continue to be an emerging growth company, we do intend to take advantage of certain other exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, exemptions from the requirements of holding a nonbinding advisory stockholder vote on executive compensation and any golden parachute payments not previously approved, and exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis). As a result of our reliance on these exemption, the information that we provide stockholders may be different than what is available with respect to other public companies. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If investors find our common stock less attractive as a result of our status as an emerging growth company, there may be less liquidity for our common stock and our stock price may be more volatile.

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 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.

Recent 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 recently enacted significant tax reform, 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, and April 2018, we announced positive interim results from an ongoing low-dose Phase 2 study of seladelpar in patients with PBC. During the fourth quarter of 2017, we initiated enrollment in a long-term extension study of seladelpar in patients with PBC. In April 2018, we initiated screening in a Phase 2b study of seladelpar in patients with NASH. 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 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 never conducted 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 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 testing of seladelpar in clinical studies for the indications that we are currently pursuing for seladelpar, including primary biliary cholangitis (PBC) and non-alcoholic steatohepatitis (NASH). If seladelpar does not demonstrate safety or efficacy in the treatment, 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 which we currently are pursuing, including PBC and NASH. Seladelpar may not be demonstrated to be effective in treatment of these or other indications we may target. Although we believe that seladelpar may be beneficial to address the diseases for which we are considering directing its development, 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. 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; and
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials.

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);
- 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 some of the targeted indications for seladelpar but not 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 adequate reimbursement and pricing by third parties 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 and any related compensation with respect to clinical studies could adversely affect the 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, from time to time and 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 future 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 new drug application (NDA) 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 has 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 authorities 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 NDA or other 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 and 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.

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 will 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 health 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;
- HIPAA, as amended by 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 or marketing expenditures.

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, exclusion from government funded health care programs, such as Medicare and Medicaid, 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.

Recently enacted 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, in March 2010, the PPACA was enacted to broaden access to health insurance, reduce or constrain the growth of health care spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The PPACA revises the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the new 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, and we expect there will be additional challenges and amendments to it in the future. 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.

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 and proposed bills 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. 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 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. Prior to commercial launch, we plan on entering into agreements with one or more pharmaceutical product packager/distributor to ensure proper supply chain management once we are authorized to make commercial sales of our product candidates. If we receive marketing approval from the FDA, we intend to sell pharmaceutical product packaged and distributed by such suppliers. Although we have entered into agreements with our current contract manufacturers and packager/distributor for clinical trial material, we may be unable to maintain an agreement on commercially reasonable terms, which could 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 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 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 foreign 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;
- 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 intellectual property by CSPs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. 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 not 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.

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 marketing and sales 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, we intend to enter into agreements with third parties to market those product candidates outside the United States, including for seladelpar. 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;
- 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 treatments the 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 and our other product candidates, which could make it difficult for us to sell our products profitably.

Obtaining formulary approval can be an expensive and time consuming process. We cannot be certain if and when we will obtain formulary approval to allow us to promote our product candidates, including seladelpar, into our target markets. Failure to obtain timely formulary approval will limit our commercial success.

Furthermore, market acceptance and sales of arhalofenate, 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.

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, 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 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:

1) 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 PPARδ Products and are required to use diligent efforts to conduct all such activities. If we fail to comply with our obligations under our agreement with Janssen NV, including our obligations to expend more than a de minimus 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.

2) We rely on an exclusive license to certain patents, proprietary technology and know-how from DiaTex, which include arhalofenate. During the term of the exclusive license with DiaTex we may perform research and development of compounds and products for the treatment of human disease based on the patents, proprietary technology and know-how from DiaTex. If we fail to comply with our obligations under our agreement with DiaTex, including our obligations to pay royalty payments during the development and commercialization of arhalofenate, or if we are subject to a bankruptcy, DiaTex 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 DiaTex license, arhalofenate, which could have an 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 of June 30, 2018, we had 35 full-time employees. 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, the Health Insurance Portability and Accountability Act of 1996, or 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 Capital 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 Capital 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 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;
- 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.

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

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales, or sales, at any level, by insiders that are reported on Form 4, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

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 $91.3 million. In addition, in December 2017 we filed a $200 million shelf registration statement on Form S-3 with the SEC, and 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. 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 June 30, 2018, was 1,605,403 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. In addition, our ability to pay cash dividends is currently prohibited without the prior consent of the lender pursuant to the terms of our 2015 loan and security agreements.

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.
4.2	Form of Registration Rights Agreement (Filed with the SEC as Exhibit 4.2 to our Amendment No. 2 to Registration Statement on Form 10, filed with the SEC on October 17, 2013, SEC File No. 000-55021).
4.3	Amendment No. 1 to Registration Rights Agreement. (Filed with the SEC as Exhibit 4.4 to our Form 10-K, filed with the SEC on March 31, 2014, SEC File No. 000-55021).
4.4	Form of 2013 Financing Warrant (Filed with the SEC as Exhibit 4.3 to our Amendment No. 2 to Registration Statement on Form 10, filed with the SEC on October 17, 2013, SEC File No. 000-55021).
10.1	CymaBay Therapeutics, Inc. 2013 Equity Incentive Plan (Filed with the SEC as Exhibit 10.1 to our Form 8-K, filed with the SEC on June 7, 2018, SEC File No. 000-36500).
10.2	First Amendment to Lease, dated April 16, 2018, between BMR-Pacific Research Center LP and CymaBay Therapeutics, Inc. (Filed with the SEC as Exhibit 10.1 to our Form 10-Q, filed with the SEC on May 8, 2018, SEC File No. 000-555021).
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	XBRL Instance Document
101.SCH	XBRL Taxonomy Schema Linkbase Document
101.CAL	XBRL Taxonomy Calculation Linkbase Document
101.DEF	XBRL Taxonomy Definition Linkbase Document
101.LAB	XBRL Taxonomy Labels Linkbase Document
101.PRE	XBRL Taxonomy Presentation Linkbase Document

SIGNATURES

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

CYMABAY THERAPEUTICS, INC.

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

Date: August 9, 2018

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

Date: August 9, 2018

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: August 9, 2018

/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: August 9, 2018

/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 June 30, 2018, 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 August 9, 2018.

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