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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 10-Q**

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(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2016

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

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**CymaBay Therapeutics, Inc.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

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

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

**94560**  
(Zip Code)

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

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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, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting 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

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

As of October 31, 2016, there were 23,447,003 shares of the registrant’s Common Stock outstanding.

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**CYMABAY THERAPEUTICS, INC.**  
**QUARTERLY REPORT ON FORM 10-Q**  
**FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2016**

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**PART I. FINANCIAL INFORMATION**

**Item 1. Financial Statements**

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

	<b>September 30, 2016 (unaudited)</b>	<b>December 31, 2015</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 6,821	\$ 7,706
Marketable securities	16,313	33,774
Accrued interest receivable	22	186
Prepaid expenses	1,324	1,128
Total current assets	24,480	42,794
Property and equipment, net	85	64
Other assets	221	221
Total assets	<u>\$ 24,786</u>	<u>\$ 43,079</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 935	\$ 1,008
Accrued liabilities	2,960	3,336
Warrant liability	1,177	1,220
Facility loan	2,607	509
Accrued interest payable	72	73
Total current liabilities	7,751	6,146
Facility loan, less current portion	6,809	8,799
Other liabilities	14	19
Total liabilities	14,574	14,964
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value: 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, \$0.0001 par value: 100,000,000 shares authorized; 23,447,003 shares issued and outstanding as of September 30, 2016 and December 31, 2015	2	2
Additional paid-in capital	426,219	424,422
Accumulated other comprehensive loss	(2)	(21)
Accumulated deficit	(416,007)	(396,288)
Total stockholders' equity	10,212	28,115
Total liabilities and stockholders' equity	<u>\$ 24,786</u>	<u>\$ 43,079</u>

*See accompanying notes.*

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Operating expenses:				
Research and development	\$ 3,534	\$ 4,528	\$ 12,093	\$ 12,975
General and administrative	2,130	2,201	6,806	7,075
Total operating expenses	5,664	6,729	18,899	20,050
Loss from operations	(5,664)	(6,729)	(18,899)	(20,050)
Other income (expense):				
Interest income	45	46	146	99
Interest expense	(341)	(265)	(1,009)	(584)
Other income, net	81	1,083	43	10,985
Net loss	\$ (5,879)	\$ (5,865)	\$ (19,719)	\$ (9,550)
Net loss	\$ (5,879)	\$ (5,865)	\$ (19,719)	\$ (9,550)
Other comprehensive income:				
Unrealized gain on marketable securities, net of tax	3	5	19	6
Other comprehensive income	3	5	19	6
Comprehensive loss	\$ (5,876)	\$ (5,860)	\$ (19,700)	\$ (9,544)
Basic net loss per common share	\$ (0.25)	\$ (0.27)	\$ (0.84)	\$ (0.55)
Diluted net loss per common share	\$ (0.25)	\$ (0.27)	\$ (0.84)	\$ (0.58)
Weighted average common shares outstanding used to calculate basic net loss per common share	23,447,003	21,674,742	23,447,003	17,368,309
Weighted average common shares outstanding used to calculate diluted net loss per common share	23,447,003	21,674,742	23,447,003	17,384,000

*See accompanying notes.*

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

	<b>Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2016</b>	<b>2015</b>
<b>Operating activities</b>		
Net loss	\$(19,719)	\$ (9,550)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	21	17
Stock based compensation expense	1,797	1,874
Amortization of premium on marketable securities	128	347
Non-cash interest associated with debt discount accretion	352	152
Change in fair value of warrant liability	(43)	(10,985)
Changes in assets and liabilities:		
Contract receivables	—	211
Accrued interest receivable	164	(73)
Prepaid expenses	(196)	500
Other assets	—	14
Accounts payable	(73)	(1,378)
Accrued liabilities	(376)	629
Accrued interest payable	(1)	109
Other liabilities	(5)	5
Net cash used in operating activities	(17,951)	(18,128)
<b>Investing activities</b>		
Purchases of property and equipment	(42)	—
Purchases of marketable securities	(19,304)	(41,772)
Proceeds from maturities of marketable securities	36,656	24,478
Net cash provided by (used in) investing activities	17,310	(17,294)
<b>Financing activities</b>		
Proceeds from issuance of common stock and warrants, net of issuance costs	—	25,375
Proceeds from facility loan, net	—	9,482
Repayment of loan principal	(244)	(4,756)
Proceeds from issuance of common stock upon warrant exercises	—	426
Net cash (used in) provided by financing activities	(244)	30,527
Net decrease in cash and cash equivalents	(885)	(4,895)
Cash and cash equivalents at beginning of period	7,706	11,586
Cash and cash equivalents at end of period	<u>\$ 6,821</u>	<u>\$ 6,691</u>

*See accompanying notes.*

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

#### **1. Organization and Description of Business**

CymaBay Therapeutics, Inc. (the “Company” or “CymaBay”) is a biopharmaceutical company focused on developing therapies to treat diseases with high unmet medical need, including serious rare and orphan disorders. The Company’s two key clinical development candidates are MBX-8025 and arhalofenate. MBX-8025 is currently being developed for the treatment of various orphan liver and lipid diseases. Arhalofenate is being developed for the treatment of gout. The Company was incorporated in Delaware in October 1988 as Transtech Corporation. The Company’s headquarters and operations are located in Newark, California and it operates in one segment.

#### **Liquidity**

The Company has incurred net operating losses and negative cash flows from operations since its inception. During the nine months ended September 30, 2016, the Company incurred a net loss of \$19.7 million and used \$18.0 million of cash in operations. At September 30, 2016, the Company had an accumulated deficit of \$416.0 million. CymaBay expects to incur increased 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 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.

As of September 30, 2016, the Company’s cash, cash equivalents and marketable securities totaled \$23.1 million. These funds are expected to satisfy the Company’s liquidity requirements through at least the second quarter of 2017. 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 timing of initiation of planned clinical trials, including additional phase 2 trials to study the therapeutic benefits of MBX-8025 on patients with certain orphan diseases, including primary biliary cholangitis (PBC), as well as a phase 3 clinical trial to study the therapeutic benefits of arhalofenate on patients with gout. The Company will therefore continue to require additional financing to develop its products and fund future operating losses and will seek funds through equity financings, debt, collaborative or other arrangements with corporate sources, or through other sources of financing. It is unclear if or when any such financing transactions will occur, on satisfactory terms or at all. 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, the Company may be required to reduce development activities or to close its business, which could have an adverse impact on its ability to achieve its business objectives.

#### **2. Summary of Significant Accounting Policies**

##### **Basis of Presentation**

The accompanying interim condensed financial statements are unaudited. These unaudited interim financial statements have been prepared in accordance 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. In management’s opinion, the unaudited interim condensed financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, which include only 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, 2015, which is contained in the Company’s Annual Report on Form 10-K as filed with the SEC on March 29, 2016. The results for the three and nine months ended September 30, 2016, are not necessarily indicative of results to be expected for the year or for any other period.

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### **Use of Estimates**

The condensed 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 financial statements and accompanying notes. Management bases its estimates on historical experience and on assumptions believed to be reasonable under the circumstances. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes, and management must select an amount that falls within that range of reasonable estimates. Actual results could differ materially from those estimates. The Company believes significant judgment is involved in estimating stock-based compensation, accrued clinical expenses, and equity instrument valuations.

### **Fair Value of Financial Instruments**

The Company's financial instruments during the periods reported consist of cash and cash equivalents, marketable securities, accrued interest receivable, prepaid expenses, 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, accrued interest receivable, prepaid expenses, 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, 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—Inputs which include 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.



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Description	As of September 30, 2016			
	<i>(In thousands)</i>			
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents:				
Money market funds	\$6,714	\$ —	\$ —	\$ 6,714
Short-term investments:				
Commercial paper	—	8,689	—	8,689
Corporate debt securities	—	4,714	—	4,714
Asset-backed securities	—	2,910	—	2,910
Total assets measured at fair value	<u>\$6,714</u>	<u>\$16,313</u>	<u>\$ —</u>	<u>\$ 23,027</u>
Warrant liability	<u>\$ —</u>	<u>\$ —</u>	<u>\$1,177</u>	<u>\$ 1,177</u>
Total liabilities measured at fair value	<u>\$ —</u>	<u>\$ —</u>	<u>\$1,177</u>	<u>\$ 1,177</u>

Description	As of December 31, 2015			
	<i>(In thousands)</i>			
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents:				
Money market funds	\$6,942	\$ —	\$ —	\$ 6,942
Short-term investments:				
Commercial paper	—	5,992	—	5,992
Government debt securities	—	1,507	—	1,507
Corporate debt securities	—	21,654	—	21,654
Asset-backed securities	—	4,621	—	4,621
Total assets measured at fair value	<u>\$6,942</u>	<u>\$33,774</u>	<u>\$ —</u>	<u>\$ 40,716</u>
Warrant liability	<u>\$ —</u>	<u>\$ —</u>	<u>\$1,220</u>	<u>\$ 1,220</u>
Total liabilities measured at fair value	<u>\$ —</u>	<u>\$ —</u>	<u>\$1,220</u>	<u>\$ 1,220</u>

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

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 classified as liabilities and recorded at fair value using a binomial lattice option-pricing model, the inputs for which include the exercise price of the warrants, market price of the underlying common shares, expected term, volatility, the risk-free rate, and the expected changes in stock price that follow announcements of the Company's clinical trial results and other strategic initiatives. Changes to any of the inputs to the valuation model used by the Company can have a significant impact to the estimated fair value of the warrants.

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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 Nine Months Ended September 30,	
	2016	2015
Balance, beginning of period	\$1,220	\$ 13,596
Issuance of financial instrument	—	258
Change in fair value	(43)	(10,985)
Settlement of financial instrument	—	(1,513)
Balance, end of period	<u>\$1,177</u>	<u>\$ 1,356</u>

### **Cash, 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 primarily of deposits with commercial banks in checking, interest-bearing, and demand money market accounts.

The Company invests excess cash in marketable securities with high credit ratings. These securities consist primarily of corporate debt and asset-backed securities and are classified as "available-for-sale." Management may liquidate any of these investments in order to meet the Company's liquidity needs in the next year. Accordingly, any investments with contractual maturities greater than one year from the balance sheet date are classified as short-term in the condensed balance sheets.

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. 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.

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Marketable securities in the condensed balance sheets, all of which are classified as available-for-sale, consisted of the following (in thousands):

	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>
As of September 30, 2016:				
Short-term investments:				
Commercial paper	8,689	—	—	8,689
Corporate debt securities	4,716	—	(2)	4,714
Asset-backed securities	2,910	—	—	2,910
	<u>\$ 16,315</u>	<u>\$ —</u>	<u>\$ (2)</u>	<u>\$ 16,313</u>
As of December 31, 2015:				
Short-term investments:				
Commercial paper	5,992	—	—	5,992
Government debt securities	1,509	—	(2)	1,507
Corporate debt securities	21,671	—	(17)	21,654
Asset-backed securities	4,623	—	(2)	4,621
	<u>\$ 33,795</u>	<u>\$ —</u>	<u>\$ (21)</u>	<u>\$ 33,774</u>

At September 30, 2016, and December 31, 2015, the remaining contractual maturities of the Company's commercial paper, corporate debt securities, and government debt securities was less than one year and asset backed securities was between two and five years. Realized gains and losses were immaterial for all periods presented. None of these investments has been in a continuous unrealized loss position for more than 12 months as of September 30, 2016, or December 31, 2015.

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### **Restricted Cash**

The Company is required to maintain compensating cash balances with financial institutions that provide the Company with its corporate credit cards. As of September 30, 2016, and December 31, 2015, cash restricted under these arrangements was \$170,000. This amount is presented in other assets on the accompanying condensed balance sheets.

### **Concentration of Credit 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 condensed balance sheets. 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 counterparties to the agreements relating to the Company's investments consist of financial institutions of high credit standing.

### **Common Stock Warrant Liability**

Warrants issued to common stock holders and lenders by the Company in conjunction with financings from 2013 through 2015 are classified as liabilities in the accompanying condensed balance sheets, as the terms for redemption of the underlying security are outside the Company's control. The warrants are recorded at fair value and are re-measured at each financial reporting period until the warrants are exercised or expire and immediately before exercise, with any changes in fair value being recognized as a component of other income (expense), net in the accompanying condensed statements of operations and comprehensive loss.

### **Research and Development Expenses**

Research and development expenses consist of costs incurred in identifying, developing, and testing product candidates. These expenses consist primarily of costs for research and development personnel (including related stock-based compensation); contract research organizations and other third parties that assist in managing, monitoring, and analyzing clinical trials; investigator and site fees; laboratory services; consultants; contract manufacturing services; non-clinical studies, including materials; and allocated expenses, such as depreciation of assets, and facilities and information technology that support research and development activities. Research and development costs are expensed as incurred, including expenses that may or may not be reimbursed under research and development funding arrangements.

The expenses related to clinical trials are based upon estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations (CROs) that conduct and manage clinical trials on behalf of the Company. Expenses related to clinical trials are accrued based upon the level of activity incurred under each contract as indicated by such factors as progress made against specified milestones or targets in each period, patient enrollment levels, and other trial activities as reported by CROs. Accordingly, the Company's clinical trial accrual is dependent upon the timely and accurate reporting of expenses by clinical research organizations and other third-party vendors. Payments made to third parties under these clinical trial arrangements in advance of the receipt of the related services are recorded as prepaid assets, depending on the terms of the agreement, until the services are rendered.

### **Stock-Based Compensation**

Employee and director stock-based compensation is measured at the grant date, based on the fair-value of the awards, and the portion that is ultimately expected to vest is recognized as an expense over the related vesting periods, net of estimated forfeitures. The Company calculates the fair-value of option grants and incentive awards using the Black-Scholes model and recognizes expense using the straight-line attribution method. For performance based stock options, the Company begins to recognize the expense when it is deemed probable that the performance based condition will be met. The Company evaluates the probability of achieving performance based condition at each reporting period.

Equity awards granted to non-employees are valued using the Black-Scholes option pricing model to determine the fair value of such instruments. The fair value of equity awards granted to non-employees are re-measured throughout the related vesting period and amortized to expense over that period.

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### Net Loss Per Common Share

Basic net loss per share of common stock is calculated as the weighted average number of shares of common stock outstanding equivalents during the period. Diluted net loss per share of common stock is calculated as the weighted average number of shares of common stock outstanding adjusted to include the assumed exercises of stock options and 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 warrants and the presumed exercise of such securities are dilutive to earnings (loss) per share for the period, adjustments to net income or net loss used in the calculation are required to remove the change in fair value of the warrants for the period. Likewise, adjustments to the denominator are required to reflect the related dilutive shares.

In all periods presented, the Company's outstanding stock options and incentive awards were excluded from the calculation of net loss per share because the effect would be antidilutive.

The Company's computation of net loss per share is as follows (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
<b>Numerator:</b>				
Net loss allocated to common stock-basic	\$ (5,879)	\$ (5,865)	\$ (19,719)	\$ (9,550)
Adjustments for revaluation of warrants	—	—	—	(505)
Net loss allocated to common stock-diluted	\$ (5,879)	\$ (5,865)	\$ (19,719)	\$ (10,055)
<b>Denominator:</b>				
Weighted average number of common stock shares outstanding—basic	23,447,003	21,674,742	23,447,003	17,368,309
Dilutive Securities:				
Common stock warrants	—	—	—	15,691
Weighted average number of common stock shares outstanding—diluted	23,447,003	21,674,742	23,447,003	17,384,000
<b>Net loss per share—basic:</b>	\$ (0.25)	\$ (0.27)	\$ (0.84)	\$ (0.55)
<b>Net loss per share—diluted:</b>	\$ (0.25)	\$ (0.27)	\$ (0.84)	\$ (0.58)

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 September 30,		Nine Months September 30,	
	2016	2015	2016	2015
Warrants for common stock	1,667	1,667	1,667	1,492
Common stock options	2,422	1,785	2,422	1,785
Performance-based stock options	327	—	327	—
Incentive awards	241	245	241	245
	4,657	3,697	4,657	3,522

### Recent Accounting Pronouncements

#### *Accounting Standards Update 2014-15*

In August 2014, the FASB issued guidance codified in ASC 205, Presentation of Financial Statements — Going Concern. Accounting Standards Update 2014-15 requires an entity's management to evaluate whether there are conditions or events, considered

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in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern and if those conditions exist, to make the required disclosures. Early adoption will be permitted. The standard is effective for annual periods ending after December 15, 2016, and for annual and interim periods thereafter. The Company does not expect that the adoption of this standard will have a significant impact on its condensed financial statements.

### *Accounting Standards Update 2015-03*

In April 2015, the FASB issued ASU No. 2015-03, Interest—Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs, which requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction from the corresponding debt liability rather than as an asset. The Company adopted this ASU with retrospective application in the first quarter of 2016. As the Company does not have any debt issuance costs recorded as assets, the adoption of this standard did not have any impact on its condensed financial statements.

### *Accounting Standards Update 2016-02*

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The ASU requires management to recognize lease assets and lease liabilities by lessees for most leases. The ASU is effective for the annual periods beginning after December 15, 2018 and interim periods therein on a modified retrospective basis. The Company is currently evaluating the impact this guidance will have on its condensed financial statements.

### *Accounting Standards Update 2016-09*

In March 2016, the FASB issued ASU No. 2016-09, Improvements to Employee Share-Based Payment Accounting, which amends ASC Topic 718, Compensation – Stock Compensation. The ASU includes provisions intended to simplify various aspects related to how share-based payments are accounted for and presented in the financial statements. The ASU will be effective for the Company for the annual periods beginning after December 15, 2016 and interim periods within those annual periods on a modified retrospective basis. The Company is currently evaluating the impact this guidance will have on its condensed financial statements.

### *Accounting Standards Update 2016-13*

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments – Credit Losses (Topic 326), which introduces an approach based on expected losses to estimate credit losses on certain types of financial instruments. It also modifies the impairment model for available-for-sale debt securities and provides for a simplified accounting model for purchased financial assets with deterioration since their origination. The ASU is effective for the annual periods beginning after December 15, 2019 including interim periods within those annual periods. The Company is currently evaluating the impact this guidance will have on its condensed financial statements.

## **3. Certain Balance Sheet Items**

Accrued liabilities consist of the following (in thousands):

	<b>September 30, 2016</b>	<b>December 31, 2015</b>
	<b>(unaudited)</b>	
Accrued compensation	\$ 1,399	\$ 1,010
Accrued pre-clinical and clinical trial expenses	1,244	2,015
Accrued professional fees	269	283
Other accruals	48	28
Total accrued liabilities	<u>\$ 2,960</u>	<u>\$ 3,336</u>

## **4. Common Stock Warrants**

During the three and nine months ended September 30, 2015, the Company issued an aggregate of 9,703 and 132,295 shares of common stock, respectively, to stockholders upon the exercise of warrants exercisable for shares of the Company's common stock. The 132,295 shares of common stock were issued pursuant to both cash and net exercise provisions as provided in the warrants. Specifically, 74,136 shares of the Company's common stock were issued in exchange for \$0.4 million in cash and 58,159 shares of the

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Company's common stock were issued in exchange for shares of its common stock in accordance with net exercise provisions. For each warrant exercised, the Company determined the warrant's exercise date fair value and reclassified the fair value of such settled warrants from the warrant liability to additional paid-in capital, a component of stockholder's equity. The aggregate amount of these fair value reclassifications totaled \$0.2 million and \$1.5 million during the three and nine months ended September 30, 2015, respectively. No warrants were issued or exercised for the three and nine months ended September 30, 2016.

### **5. Collaboration and License Agreements**

#### ***Janssen Pharmaceutical NV and Janssen Pharmaceuticals, Inc.***

In June 2006, the Company entered into an exclusive worldwide, royalty-bearing license to MBX-8025 and certain other PPARd compounds (the "PPARd Products") with Janssen Pharmaceutical NV (Janssen NV), with the right to grant sublicenses to third parties to make, use and sell such PPARd Products. Under the terms of the agreement, the Company has full control and responsibility over the research, development and registration of any PPARd Products and is required to use diligent efforts to conduct all such activities. Janssen NV has the sole responsibility for the preparation, filing, prosecution, maintenance of, and defense of the patents with respect to, the PPARd Products. Janssen NV has a right of first negotiation under the agreement to license a particular PPARd 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 PPARd Products. Under the terms of the agreement Janssen NV is entitled to receive up to an 8% royalty on net sales of PPARd 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 T2DM and other disorders and received a one-time nonrefundable technology access fee related to the agreements. 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 pursuant to the terms of one of the original agreements to continue work to research, develop and commercialize compounds with activity against an undisclosed metabolic disease target. Janssen granted the Company an exclusive, worldwide license (with rights to sublicense) under the Janssen know-how and patents to research, develop, make, have made, use, offer for sale and sell such compounds. The Company has full control and responsibility over the research, development and registration of any products developed and/or discovered from the metabolic disease target and is required to use diligent efforts to conduct all such activities.

#### ***Dia Tex, 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 of 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 \$2,000 per month license fee as well as a requirement to make additional payments for development achievements and royalty payments on any sales of licensed products. DiaTex is entitled to up to \$0.8 million for the future development of arhalofenate, as well as royalty payments on any sales of products containing arhalofenate. No development payments were made in the three and nine months ended September 30, 2016 and 2015 and no royalties have been paid to date.

### **6. Facility Loans**

#### ***2013 Term Loan Facility***

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) for a total loan amount of \$10.0 million of which the first tranche of \$5.0 million was drawn as part of the Company's September 2013 financing, referred to herein as the 2013 Term Loan Facility. The loan had a fixed interest rate of 8.75% payable as interest only for twelve months and a thirty-six month loan amortization period thereafter, with a final interest payment of \$0.3 million at the end of the loan period. The second tranche of \$5.0 million became available to the Company upon its February 24, 2015, announcement of the achievement of positive Phase 2b data for the Company's product candidate arhalofenate and remained available to the Company until June 30, 2015. On June 30, 2015, the second tranche portion of the loan facility expired unused by the Company.

At the time the first \$5.0 million tranche of the facility loan was drawn down, the Company 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. Upon issuance, the fair value of a warrant liability was recorded and is being revalued at each balance sheet date until the warrants are exercised or expire.

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### *2015 Term Loan Facility*

On August 7, 2015, the Company entered into a Loan and Security Agreement pursuant to which it refinanced its existing 2013 Term Loan Facility with Oxford Finance LLC and Silicon Valley Bank, for an aggregate amount of up to \$15.0 million, referred to herein as the 2015 Term Loan Facility. The first \$10.0 million tranche of this new loan facility was made available to the Company immediately upon the closing and was used in part to retire all \$4.1 million of the Company's existing debt outstanding under the 2013 Term Loan Facility, and to settle accrued interest and closing costs with the lenders. The remaining \$5.0 million, referred to as the second tranche, was made available to the Company until March 31, 2016, for draw down upon the announcement of a qualified out-license or co-development arrangement for arhalofenate, the Company's gout therapy drug candidate, which includes an upfront payment of not less than \$35.0 million (the second draw milestone). Because the present value of the future cash flows under the modified loan terms did not exceed the present value of the future cash flows under the previous loan terms by more than 10%, the Company treated this refinancing as a modification. The remaining debt discount costs will be amortized over the remaining term of the Loan and Security Agreement using the effective interest rate method. The \$5.0 million second tranche expired unused in March 2016 as the second draw milestone was not achieved.

The first loan tranche bears interest at 8.77%, a rate which was determined on the advance date as being the greater of (i) 8.75% and (ii) the sum of 8.47% and the 90 day U.S. LIBOR rate reported in the Wall Street Journal three business days prior to the funding date of the first tranche. Under the first tranche, the Company is required to make 12 monthly interest only payments after the funding date followed by a repayment schedule equal to 36 equal monthly payments of interest and principal. Upon maturity, the remaining balance of the first tranche and a final payment equal to 6.50% of the original principal amount advanced of the applicable tranche are payable.

At the closing, the Company also agreed to pay a facility fee of 1.00% of the 2015 Term Loan Facility commitment. In addition, 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. Upon issuance, the fair value of a warrant liability of \$0.3 million was recorded in the accompanying condensed balance sheet and is being revalued at each balance sheet date until the warrants are exercised or expire.

The 2015 Term Loan Facility contains customary representations and warranties and customary affirmative and negative covenants applicable to the Company, and also includes defined customary events of default. As of September 30, 2016, the Company was in compliance with the term loan covenants and there were no events of default.

## **7. 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 December 31, 2018. Rent expense was \$0.1 million for each of the three months ended September 30, 2016 and 2015, and \$0.3 million for each of the nine months ended September 30, 2016 and 2015.

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

	<b>Lease Payments</b>
Year ending December 31:	
2016 (from October to December)	\$ 54
2017	222
2018	228
Total future minimum payments	<u>\$ 504</u>

## **Indemnification**

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnification, including indemnification associated with product liability or infringement of intellectual property rights. The Company's exposure under these agreements is unknown because it involves future claims that may be made against the Company that may be, but have not yet been, made. To date, the Company has not paid any claims or been required to defend any action related to these indemnification obligations, and no amounts have been accrued in the accompanying consolidated balance sheets related to these indemnification obligations.

The Company has agreed to indemnify its executive officers and directors for losses and costs incurred in connection with certain events or occurrences, including advancing money to cover certain costs, subject to certain limitations. The maximum potential amount of future payments the Company could be required to make under this indemnification is unlimited; however, the Company maintains insurance policies that may limit its exposure and may enable it to recover a portion of any future amounts paid. Assuming the applicability of coverage, the willingness of the insurer to assume coverage, and subject to certain retention, loss limits, and other policy provisions, the Company believes the fair value of these indemnification obligations is not material. Accordingly, the Company



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has not recognized any liabilities relating to these obligations as of September 30, 2016, and December 31, 2015. No assurances can be given that the covering insurers will not attempt to dispute the validity, applicability, or amount of coverage without expensive litigation against these insurers, in which case the Company may incur substantial liabilities as a result of these indemnification obligations.

### 8. Stockholders' Equity

The Company is authorized to issue 10,000,000 shares of preferred stock with a par value of \$0.0001 per share as of September 30, 2016. The Company is authorized to issue 100,000,000 shares of common stock with a par value of \$0.0001 per share as of September 30, 2016.

As of September 30, 2016 and December 31, 2015, the Company had reserved shares of authorized but unissued common stock as follows:

	<b>September 30, 2016</b>	<b>December 31, 2015</b>
	<b>(unaudited)</b>	
Common stock warrants	1,667,398	1,667,398
Equity incentive plans	3,456,771	2,284,421
Total reserved shares of common stock	<u>5,124,169</u>	<u>3,951,819</u>

### 9. Stock Plans and Stock-Based Compensation

#### Stock Plans

On January 1, 2016, the share reserve of the Company's 2013 Equity Incentive Plan ("2013 Plan"), automatically increased by 1,172,350 shares. As of September 30, 2016, there were 466,445 shares available for issuance under the 2013 Plan.

#### Stock-Based Compensation Expense

Stock-based compensation expense recorded, net of estimated forfeitures, was as follows (in thousands):

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
	<b>(unaudited)</b>		<b>(unaudited)</b>	
Research and development	\$ 273	\$ 213	\$ 718	\$ 607
General and administrative	394	349	1,079	1,245
Total	<u>\$ 667</u>	<u>\$ 562</u>	<u>\$1,797</u>	<u>\$1,852</u>

In July 2016, the Company granted 327,000 performance-based stock options (PSOs) to executives and senior officers. PSOs represent a contingent right to purchase the Company's common stock upon the achievement of specific conditions. Specifically, these PSOs vest upon the achievement of certain clinical development and capital raising milestones which must occur before December 31, 2016. As of September 30, 2016, the achievement of the clinical development milestone was deemed to be probable and the related pro rata expense was recognized for the three and nine months then ended. As of September 30, 2016, unrecognized stock-based compensation related to these PSOs is \$304,000 and its recognition is dependent upon the achievement of the milestones.

### 10. Related-Party Transactions

The Company paid a former member of its Board of Directors, who is also a scientific and clinical advisor, a total of \$60,000 in the year ended December 31, 2015 and \$45,000 for the nine months ended September 30, 2016, in monthly cash retainers. The Company also granted 9,000 options to purchase shares of common stock to this individual in his capacity as a key scientific advisor for the nine months ended September 30, 2016.

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

*Operating results for the three and nine months ended September 30, 2016, 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 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; our expectations with respect to regulatory submissions and approvals; our drug discovery technologies; our research and development expenses; protection of our intellectual property; sufficiency of our cash and capital resources and the need for additional capital; and our operations and legal risks. You should not place undue reliance on these forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including as a result of the risks and uncertainties discussed under the heading “Risk Factors” in Item 1A of Part II of this Quarterly Report on Form 10-Q. Any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.*

#### **Overview**

CymaBay Therapeutics, Inc. is focused on developing therapies to treat diseases with high unmet medical need, including serious rare and orphan disorders. Our two key clinical development candidates are MBX-8025 and arhalofenate.

We are currently developing MBX-8025 for the treatment of various orphan liver and lipid diseases. In May 2016, we announced results from a Phase 2 clinical study of MBX-8025 in patients with primary biliary cholangitis (PBC). The study was intended to enroll approximately 75 patients with PBC who had an inadequate response to ursodiol and randomize them to receive either placebo or MBX-8025 (either 50 mg or 200 mg) once-daily for 12 weeks. Despite the occurrence of three cases of asymptomatic, reversible transaminase elevations (two in the 200 mg and one in the 50 mg cohorts), data from 35 patients evaluated for efficacy demonstrated that treatment with MBX-8025 resulted in statistically significant reductions in the primary endpoint of alkaline phosphatase (ALP). The mean decreases from baseline in ALP for the 50 and 200 mg dose groups were 53% and 63%, respectively, vs. 2% for placebo ( $p < 0.0001$  for both). We made the decision to discontinue the study early after review of safety and efficacy data demonstrated clear proof-of-concept and need for further dose reduction to optimize clinical safety and efficacy. We intend to initiate a dose-ranging Phase 2 trial of MBX-8025 at lower doses in patients with PBC. In October 2016, MBX-8025 received European Medicines Agency (EMA) PRiority Medicines (PRIME) designation for the treatment of PBC. In March 2016, we announced data from a second Phase 2 clinical study evaluating MBX-8025 in 13 patients with homozygous familial hypercholesterolemia (HoFH). Five patients in this study experienced what we believe was a clinically meaningful maximal decrease in low density lipoprotein (LDL-C) of greater than 20% with three of them having decreases greater than 30%. However, given the variability in responses observed in this study, including a number of patients that did not experience a decrease in LDL-C, we believe additional proof-of-concept data would be warranted before determining whether or not to advance to a registration study of MBX-8025 in patients with HoFH. We also believe that MBX-8025 could have utility in the treatment of severe hypertriglyceridemia (SHTG) and the more prevalent, but high unmet need, indication of nonalcoholic steatohepatitis (NASH). We have obtained orphan-drug designations for MBX-8025 in PBC, HoFH and SHTG (Frederickson type I or V hyperlipoproteinemia).

Arhalofenate, is being developed for the treatment of gout. Arhalofenate has been studied in five Phase 2 clinical trials in patients with gout and consistently demonstrated the ability to reduce gout flares and reduce serum uric acid (sUA). Gout flares are recurring and painful episodes of joint inflammation that are triggered by the presence of monosodium urate crystals that form as a result of elevated sUA levels. We believe the potential for arhalofenate to prevent or reduce flares while also lowering sUA could differentiate it from currently available treatments for gout and classify it as the first potential drug in what we believe could be a new class of gout therapy referred to as Urate Lowering Anti-Flare Therapy (ULAFT). Arhalofenate has established a favorable safety profile in clinical trials involving over 1,100 patients exposed to date. We have completed end of Phase 2 discussions with the FDA and intend to partner arhalofenate prior to advancing into Phase 3 development.

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We are an emerging growth company. Under the JOBS Act emerging growth companies can delay adopting new or revised accounting standards until such time of those standards apply to private companies. We have adopted this exemption from new or revised accounting standards, and therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not “emerging growth companies.”

### **Equity Financings**

On July 25, 2014, we completed a public offering of 4.6 million shares of our common stock at \$5.50 per share which we refer to as our 2014 public offering. Net proceeds to us in connection with the 2014 public offering were approximately \$23.0 million after deducting underwriting discounts, commissions and offering expenses.

On November 7, 2014, we filed a \$100 million registration statement on Form S-3 with the SEC, which registration statement includes an at-the-market facility (ATM) to sell up to \$25 million of common stock under the registration statement. As of September 30, 2016, we have sold shares of common stock under the ATM with aggregate net proceeds to us of \$4.3 million.

On July 27, 2015, pursuant to our shelf registration statement on Form S-3, we completed the issuance of 8.2 million shares of our common stock at \$2.81 per share which we refer to as our 2015 public offering. Net proceeds to us in connection with the 2015 public offering were approximately \$21.1 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. 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. We consider certain accounting policies including, but not limited to, research and development expenses and clinical accruals, stock-based compensation and valuation of warrant liabilities to be critical policies. Actual results may materially differ from these estimates under different assumptions or conditions. There have been no significant changes in our critical accounting estimates during the nine months ended September 30, 2016, as compared with those previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, filed with the SEC on March 29, 2016.

### **Results of Operations**

#### ***General***

To date, we have not generated any income from operations. As of September 30, 2016, we had an accumulated deficit of \$416.0 million, primarily as a result of expenditures for research and development and general and administrative expenses from inception to that date. While we may in the future generate revenue from a variety of sources, including product sales, royalties and license fees and milestone payments in connection with strategic partnerships, our product candidates are still under clinical 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 significant revenue to achieve and sustain profitability.

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	Three Months Ended September 30,			Nine Months Ended September 30,		
	2016	2015	Variance	2016	2015	Variance
<i>(\$ in thousands)</i>						
<b>Operating expenses:</b>						
Research and development	\$ 3,534	\$ 4,528	\$ (994)	\$ 12,093	\$ 12,975	\$ (882)
General and administrative	2,130	2,201	(71)	6,806	7,075	(269)
Loss from operations	(5,664)	(6,729)	1,065	(18,899)	(20,050)	1,151
Interest expense, net	(296)	(219)	(77)	(863)	(485)	(378)
Other income, net	81	1,083	(1,002)	43	10,985	(10,942)
Net loss	<u>\$ (5,879)</u>	<u>\$ (5,865)</u>	<u>\$ (14)</u>	<u>\$ (19,719)</u>	<u>\$ (9,550)</u>	<u>\$ (10,169)</u>

### **Research & Development Expenses**

Conducting research and development is central to our business model. For the three months ended September 30, 2016 and 2015, research and development expenses were \$3.5 million and \$4.5 million, respectively. For the nine months ended September 30, 2016 and 2015, research and development expenses were \$12.1 million and \$13.0 million, respectively. Research and development expenses are detailed in the table below:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
<i>(\$ in thousands)</i>				
	(unaudited)		(unaudited)	
MBX-8025 Phase 2 clinical studies	\$ 1,154	\$ 1,014	\$ 4,648	\$ 1,503
MBX-8025 Drug manufacturing & toxicity studies	693	1,134	2,282	2,930
MBX-8025 Other studies	19	26	23	130
Arhalofenate Gout—Phase 2b Randomized Study	22	105	32	1,357
Arhalofenate Gout—Febuxostat Combo Study	1	—	25	177
Arhalofenate Gout — Drug manufacturing	121	940	370	2,653
Other Projects	13	5	47	39
<b>Total Project Costs</b>	<u>2,023</u>	<u>3,224</u>	<u>7,427</u>	<u>8,789</u>
Internal Research and Development Costs	<u>1,511</u>	<u>1,304</u>	<u>4,666</u>	<u>4,186</u>
<b>Total Research and Development</b>	<u>\$ 3,534</u>	<u>\$ 4,528</u>	<u>\$ 12,093</u>	<u>\$ 12,975</u>

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 decreased by \$1.2 million to \$2.0 million from \$3.2 million for the three months ended September 30, 2016 and 2015, respectively. Project costs for the three months ended September 30, 2016, primarily consist of PBC Phase 2 clinical trial expenses as well as drug manufacturing development for MBX-8025. Project costs for the three months ended September 30, 2015, consisted primarily PBC Phase 2 clinical trial expenses and other manufacturing process development activities for arhalofenate. Internal research and development cost increased by \$0.2 million for the three months ended September 30, 2016, as compared to September 30, 2015, due to higher employee compensation related expenses to support our clinical development activities.

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Total project costs decreased by \$1.4 million to \$7.4 million from \$8.8 million for the nine months ended September 30, 2016 and 2015, respectively. Project costs for the nine months ended September 30, 2016 primarily consist of PBC Phase 2 clinical trial expenses as well as drug manufacturing and toxicology studies for MBX-8025. Project costs for the nine months ended September 30, 2015, consisted primarily of PBC Phase 2 clinical trial expenses and arhalofenate Phase 2 clinical trial expenses as well as drug manufacturing costs related to registration batch production and other manufacturing process development activities for arhalofenate. Internal research and development cost increased by \$0.5 million for the nine months ended September 30, 2016, as compared to September 30, 2015, primarily due to higher employee compensation related expenses to support our 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 MBX-8025 and arhalofenate. 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. In addition, if our product development efforts are successful, we expect to incur substantial costs to prepare for potential Phase 3 clinical trials and 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 decreased by \$0.1 million, to \$2.1 million from \$2.2 million for the three months ended September 30, 2016 and 2015, respectively, primarily due to lower legal and consulting services. General and administrative expenses decreased by \$0.3 million, to \$6.8 million from \$7.1 million, for the nine months ended September 30, 2016 and 2015, respectively, primarily due to lower employee stock-based compensation. For the next several quarters, we anticipate general and administrative expenses will remain relatively consistent with current levels, given that we have completed a substantial portion of the effort required to expand our infrastructure and we have secured the professional services necessary to support us as a public reporting company under the Exchange Act.

### ***Other Income (Expense), Net***

Other income (expense), net primarily includes gains and losses resulting from the remeasurement of our investor and lender warrant liabilities at fair value. We use a binomial lattice option pricing model to value our warrants at each reporting date and the warrant valuations have historically changed primarily as a result of variations in the price of our common stock which is an input to our valuation model. However, binomial lattice option pricing models incorporate a number of other input variables, such as expected term, volatility, and other factors which, depending on the circumstances, can also impact our warrant liability valuations. 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.

Other income (expense), net for the three months ended September 30, 2016 and 2015, reflected a gain of \$0.1 million and \$1.1 million, respectively, in each case due to the remeasurement of our warrant liabilities at fair value. During the three months ended September 30, 2016, the gain recognized was due primarily to a reduction in the expected term and volatility of our investor warrants which are approaching expiration in September 2018. The changes in these variables more than offset the value enhancing impact of an increase in the price of our common stock from \$1.74 at June 30, 2016, to \$1.94 at September 30, 2016. During the three months ended September 30, 2015, the gain recognized was due primarily to a decrease in the price of our common stock from \$2.69 at June 30, 2015, to \$1.94 at September 30, 2015.

Other income (expense), net for the nine months ended September 30, 2016 and 2015, reflected a gain of \$43,000 and \$11.0 million, respectively, in each case due to the remeasurement of our warrant liabilities at fair value. Specifically, during the nine months ended September 30, 2016, the gain recognized was due primarily to a reduction in the expected term and volatility of our investor warrants which are approaching expiration in September 2018. The changes in these variables more than offset the value enhancing impact of an increase in the price of our common stock from \$1.69 at December 31, 2015, to \$1.94 at September 30, 2016. During the nine months ended September 30, 2015, the gain recognized was due primarily to a decrease in the price of our common stock from \$9.83 at December 31, 2014, to \$1.94 at September 30, 2015.

### **Liquidity and Capital Resources**

We have financed our operations primarily through the sale of equity securities, licensing fees, issuance of debt and collaborations with third parties. At September 30, 2016, we had cash, cash equivalents and marketable securities of \$23.1 million, compared to \$41.5 million at December 31, 2015.

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On July 25, 2014, we completed a public offering of 4.6 million shares of our common stock at \$5.50 per share. Net proceeds to us in connection with the 2014 public offering were approximately \$23.0 million after deducting underwriting discount, commissions and offering expenses.

On November 7, 2014, we filed a \$100 million registration statement on Form S-3 with the SEC, which registration statement includes an at-the-market facility to sell up to \$25 million of common stock under the registration statement. In January and February 2015, we sold shares of our common stock under this facility for net proceeds to us of \$4.3 million.

On July 27, 2015, pursuant to our shelf registration statement on Form S-3, we completed the issuance of 8,188,000 shares of our common stock at \$2.81 per share in an underwritten public offering. Net proceeds to us in connection with this offering were approximately \$21.1 million after deducting underwriting discounts, commissions and other offering expenses.

### *2015 Term Loan Facility*

On August 7, 2015, we entered into a new Loan and Security Agreement pursuant to which we refinanced our 2013 term loan facility with Oxford Finance LLC and Silicon Valley Bank for an aggregate amount of up to \$15 million, which we refer to as the 2015 term loan facility. The first \$10 million tranche of this new loan facility was made available to us immediately upon the closing and was used in part to retire all \$4.1 million of our existing term loan debt outstanding on the closing date, and to settle closing costs with the lenders. The remaining \$5 million, referred to as the second tranche, was available to us until March 31, 2016, for draw down upon the announcement of a qualified out-license or co-development arrangement for arhalofenate, our gout therapy drug candidate, which includes an upfront payment of not less than \$35,000,000 (the "second draw milestone"). The \$5 million second tranche expired unused in March 2016 as the second draw milestone was not achieved.

The first loan tranche bears interest at 8.77%, a rate determined on the advance date as being the greater of (i) 8.75% and (ii) the sum of 8.47% and the 90 day U.S. LIBOR rate reported in the Wall Street Journal three business days prior to the funding date of the first tranche. Under the first tranche, we are required to make 12 monthly interest only payments after the funding date followed by a repayment schedule equal to 36 equal monthly payments of interest and principal. Upon maturity, the remaining loan balance and a final payment equal to 6.50% of the original principal amount advanced are payable.

We are permitted to make voluntary prepayments of the term loans with a prepayment fee equal to 3% of the principal amount of any term loans prepaid. We are required to make mandatory prepayments of the outstanding term loans upon the acceleration by the lenders of such loans following the occurrence of an event of default, along with a payment of the final payment, the prepayment fee and any all other obligations that are due and payable at the time of the prepayment.

Our obligations under the term loan facility are secured, subject to customary permitted liens and other agreed upon exceptions, by a perfected first priority interest in all of our tangible and intangible assets, excluding our intellectual property. We also entered into a negative pledge agreement with the lenders pursuant to which we have agreed not to encumber any of our intellectual property.

The 2015 term loan facility contains customary representations and warranties and customary affirmative and negative covenants applicable to us, including, among other things, restrictions on dispositions, changes in business, management, ownership or business locations, mergers or acquisitions, indebtedness, encumbrances, distributions, investments, transactions with affiliates and subordinated debt. The representations and warranties contained in the 2015 loan facility were made only for purposes of such agreement and as of specific dates, were solely for the benefit of the parties to such agreement to allocate risk and may be subject to limitations agreed upon by the parties; accordingly, they should not be relied upon by investors as to assertions of factual matters. The 2015 term loan facility also includes customary events of default, including but not limited to the nonpayment of principal or interest, violations of covenants, material adverse change, attachment, levy, restraint on business, bankruptcy, material judgments and misrepresentations. Upon an event of default, the lenders may, among other things, accelerate the loans and foreclose on the collateral. As of September 30, 2016, we were in compliance with the terms of the term loan covenants and there were no events of default.

At the closing of the 2015 term loan facility, we also agreed to pay a facility fee of 1.00% of the 2015 term loan facility commitment. In addition, we issued warrants exercisable for a total of 114,436 shares of our common stock to the lenders at an exercise price of \$2.84 per share, and with a term of ten years.



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### Cash Flows

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

	Nine Months Ended	
	September 30,	
	2016	2015
Net cash used in operating activities	\$(17,951)	\$(18,128)
Net cash provided by (used in) investing activities	17,310	(17,294)
Net cash (used in) provided by financing activities	(244)	30,527
Net decrease in cash and cash equivalents	<u>\$ (885)</u>	<u>\$ (4,895)</u>

*Operating Activities:* Net cash used in operating activities for the nine months ended September 30, 2016, was \$17.9 million primarily due to a net loss of \$19.7 million resulting from ongoing drug development activities and other changes in operating assets and liabilities of \$0.4 million, offset by \$1.8 million of stock-based compensation and other noncash items of \$0.5 million.

*Investing Activities:* Net cash provided by investing activities was \$17.3 million for the nine months ended September 30, 2016, primarily due to net maturities of marketable securities.

*Financing Activities:* Net cash used in financing activities was \$0.2 million for the nine months ended September 30, 2016, due to the repayment of loan principal.

### Capital Requirements

As of September 30, 2016, our cash, cash equivalents and marketable securities totaled \$23.1 million. These funds will satisfy our liquidity requirements through at least the second quarter of 2017. We expect to incur substantial expenditures in the future for the development and potential commercialization of our product candidates. Because of this, we expect our future liquidity and capital resource needs will be impacted by numerous factors, including but not limited to, the timing of initiation of planned clinical trials, including phase 2 trials to study the therapeutic benefits of MBX-8025 on patients with certain orphan diseases as well as a phase 3 clinical trial to study the therapeutic benefits of arhalofenate on patients with gout. We will therefore continue to require additional financing to develop our products and fund future operating losses and will seek funds through equity financings, debt, collaborative or other arrangements with corporate sources, or through other sources of financing. It is unclear if or when any such financing transactions will occur, on satisfactory terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. If adequate funds are not available to us, we may be required to reduce our development activities or to close our business.

### Contractual Obligations and Commitments

There have been no significant changes to our aggregate contractual obligations as compared to the disclosures in our Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the SEC on March 29, 2016.

### 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

This item is not applicable to us as a smaller reporting company.

### 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 Chief Executive Officer and Chief 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.

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- (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 Chief Executive Officer and Chief 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 September 30, 2016, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **Item 1A. Risk Factors**

*During the three and nine months ended September 30, 2016, there were no material changes to the risk factors included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, other than the risk factors disclosed below. In evaluating our business, you should carefully consider the information set forth in this Quarterly Report on Form 10-Q and the risk factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K for the year ended December 31, 2015, as well as other risks and uncertainties, could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the trading price of shares of our common stock. Additional risks not currently known or currently material to us may also harm our business.*

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

We have consumed substantial amounts of capital to date as we continue our research and development activities. As of September 30, 2016, we had cash, cash equivalents and marketable securities of approximately \$23.1 million. We believe that these funds, which were obtained through recent equity and debt financings, will allow us to continue operation through at least the second quarter of 2017. We currently believe that we will need to raise additional capital to continue our operations thereafter. We will need additional capital to further develop MBX-8025 and arhalofenate which we may obtain through equity financings, debt, collaborative or other arrangements with corporate sources, or through other sources of financing. 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 research and development expenses to substantially increase in connection with our ongoing activities, particularly as we advance development of our lead clinical product candidates MBX-8025 and arhalofenate.

In the event we do not successfully raise sufficient funds in financing our product development activities, particularly related to the ongoing development of MBX-8025 and arhalofenate, 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 MBX-8025 or arhalofenate 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 MBX-8025 or arhalofenate, outlicense intellectual property rights to MBX-8025 or arhalofenate, sell assets or effect a combination of the above. No assurance can be given that we will be able to effect any of such transactions on acceptable terms, if at all. Failure to progress the development of arhalofenate and MBX-8025 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 3 studies of arhalofenate and Phase 2 studies of MBX-8025;
- 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;



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- the costs and timing of seeking and obtaining FDA and other regulatory approvals;
- the extent of our other development activities;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the effect of competing products and market developments.

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

We have incurred significant net losses in each year since our inception, including a net loss of approximately \$19.7 million for the nine months ended September 30, 2016 and \$15.5 million and \$31.9 million for the years ended December 31, 2015, and 2014, respectively. We anticipate that we will continue to incur significant losses for the foreseeable future, and we may never achieve or maintain profitability. As of September 30, 2016, we had an accumulated deficit of \$416.0 million.

To date, we have financed our operations primarily through the sale of equity securities, licensing fees, issuance of debt and collaborations with third parties. We have devoted most of our financial resources to research and development, including our preclinical development activities and clinical trials. We have not completed development of any product candidates. We expect to continue to incur significant and increasing losses and negative cash flows for the foreseeable future. The size of our losses will depend, in part, on the rate of future expenditures and our ability to generate revenues. In particular, we expect to incur substantial and increased expenses as we:

- continue the development of our product candidates MBX-8025 and arhalofenate;
- expand our research and development activities and advance our clinical programs, including MBX-8025;
- seek a partner for further development and potential commercialization of arhalofenate;
- seek to obtain regulatory approvals for arhalofenate;
- prepare for the potential commercialization of arhalofenate;
- scale up manufacturing capabilities to commercialize arhalofenate for any indications for which we receive regulatory approval;
- begin outsourcing of the commercial manufacturing of arhalofenate for any indications for which we receive regulatory approval;
- establish an infrastructure for the sales, marketing and distribution of arhalofenate for any indications for which we receive regulatory approval;
- maintain, expand and protect our intellectual property portfolio;
- continue our research and development efforts and seek to discover additional product candidates; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and commercialization efforts and operations as a public company.

We do not anticipate that we will generate revenue from the sale of our products for the foreseeable future. Our ability to become profitable depends upon our ability to generate significant continuing revenues.

In the absence of additional sources of capital, which may not be available to us on acceptable terms, or at all, the development of MBX-8025, arhalofenate or future product candidates may be reduced in scope, delayed or terminated. If our product candidates fail in clinical studies or do not gain regulatory approval, or if our future products, if any, do not achieve market acceptance, we may never become profitable.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

### **Risks Related to Clinical Development and Regulatory Approval**

*We depend on the success of our product candidates, arhalofenate and MBX-8025, which are still under clinical development and we may not obtain regulatory approval or successfully commercialize either of these product candidates.*

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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 arhalofenate, which has completed eight Phase 1 and nine Phase 2 clinical trials, including five Phase 2 studies in gout, and MBX-8025, which has completed five Phase 1 and three Phase 2 clinical trials. We had an end of phase 2 meeting with the FDA to review the results of our clinical studies and to discuss the proposed design of a phase 3 program for arhalofenate. There is no guarantee that our clinical trials will be completed or, if completed, will be successful. In March 2016, we completed a second Phase 2 clinical study for MBX-8025 in patients with homozygous familial hypercholesterolemia (HoFH). In May 2016, we announced results from a third Phase 2 clinical study of MBX-8025 in patients with primary biliary cholangitis (PBC) that we discontinued early after interim safety and efficacy data demonstrated proof-of-concept but a need for further dose reduction to optimize clinical safety and efficacy given the occurrence of elevated liver transaminases. The success of arhalofenate and MBX-8025, respectively, will depend on several factors, including the following:

- successful enrollment and completion of clinical trials;
- positive efficacy and safety data from clinical trials;
- recognition by the FDA and other regulatory authorities outside of the U.S. of orphan disease designation for MBX-8025 in target indications in addition to those already obtained;
- obtaining a partner to further develop and potentially commercialize arhalofenate;
- receipt of marketing approvals from the FDA and regulatory authorities outside the U.S. for our product candidates;
- 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 MBX-8025 or arhalofenate, which would materially harm our business.

***We depend on the successful completion of clinical trials for our product candidates, including MBX-8025 and arhalofenate. 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 MBX-8025 and arhalofenate, 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 nine Phase 2 clinical studies of arhalofenate, including five in gout. In addition, eight clinical studies with MBX-8025 and five clinical studies with MBX-2982 have been conducted. However, we have never conducted a Phase 3 clinical trial. The results we have seen to date in our Phase 2 clinical trials of MBX-8025 and arhalofenate do not ensure that later clinical trials will demonstrate similar results. 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 MBX-8025 and arhalofenate, 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;

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- 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 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 research and development expenses to increase in connection with our ongoing activities, particularly as we commence a Phase 3 clinical trial with arhalofenate and undertake additional clinical trials of our other product candidates MBX-8025 and MBX-2982. We currently plan to obtain a partner for arhalofenate before commencing the Phase 3 program. It is possible that in addition to obtaining a partner for arhalofenate, we may also be required to raise additional capital to complete Phase 3 development. We also will need to raise substantial additional capital in the future to complete the development and commercialization of MBX-8025, as well as MBX-2982 for which we currently have no planned clinical trials. 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 MBX-8025 or arhalofenate, or any other clinical trial we conduct, could require that we repeat or conduct additional clinical studies. Despite the results reported in earlier clinical trials for MBX-8025 and arhalofenate, we do not know whether any clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of our product candidates. If later stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for our product candidates, including arhalofenate, may be adversely impacted.

***We have only recently commenced testing of MBX-8025 in clinical studies for the indications which we are currently pursuing for MBX-8025, including homozygous familial hypercholesterolemia (HoFH) and Primary Biliary Cholangitis (PBC). If MBX-8025 does not demonstrate safety or efficacy in the treatment of any of these indications, or if the benefits of treatment with MBX-8025 do not outweigh the risks, our ability to successfully develop and commercialize MBX-8025 may be adversely affected.***

We have only recently commenced clinical trials of MBX-8025 for the indications for which we currently are pursuing, including HoFH and PBC and MBX-8025 may not be demonstrated to be effective in treatment of these or other indications we may target. For instance, in March 2016, we completed a Phase 2 clinical study evaluating MBX-8025 in 13 patients with HoFH. However, as a result of the variability in responses observed in this study, including a number of patients that did not experience a decrease in LDL-C, we believe additional proof-of-concept data would be warranted before determining whether or not to advance to a registration study of MBX-8025 in patients with HoFH. Although we believe that MBX-8025 may be beneficial to address the diseases for which we are considering redirecting its development, there is no guarantee that MBX-8025 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 MBX-8025 would outweigh the risks perceived from treatment with MBX-8025. In May 2016, we announced results from a Phase 2 clinical study of MBX-8025 in patients with primary biliary cholangitis (PBC) that we discontinued early after interim safety and efficacy data demonstrated proof-of-concept but a need for further dose reduction to optimize clinical safety and efficacy given the occurrence of elevated liver transaminases. Liver transaminase levels for these patients returned back to within normal range once patients discontinued treatment with MBX-8025. Although we intend to study doses of MBX-8025 below 50 mg in subsequent clinical studies in patients with PBC, there is no assurance that we will not continue to see patients experience elevated liver transaminases. A complete review of safety data from the discontinued Phase 2 clinical study is ongoing and there is no assurance that other safety signals will not adversely affect future development of MBX-8025 in patients with PBC or other patient populations.

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***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.***

Arhalofenate has been studied in a total of 17 clinical trials with over 1,100 subjects. The emergence of adverse events (AEs) caused by arhalofenate in future studies 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, including MBX-8025, 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 arhalofenate and MBX-8025, may be negatively impacted. For example, although we did not observe liver transaminase elevations in two separate Phase 2 clinical studies of MBX-8025 in patients with mixed dyslipidemia nor in patients with HoFH, we did observe this elevation in our Phase 2 clinical study of MBX-8025 in patients with PBC. There is no guarantee that we will not observe this or any other AE if we study MBX-8025 in patients with PBC at lower doses or in any other patient population that could adversely affect future development of MBX-8025.

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 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; and
- our reputation may suffer.

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

## **Item 6. Exhibits**

See the Exhibit Index which follows the signature page of this Quarterly Report on Form 10-Q, which is incorporated herein by reference.

**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/ Harold Van Wart  
Harold Van Wart  
Chief Executive Officer  
(Duly Authorized Officer and Principal  
Executive Officer)

Date: November 9, 2016

By: /s/ Sujal Shah  
Sujal Shah  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

Date: November 9, 2016

**INDEX TO EXHIBITS**

<b><u>Exhibit Number</u></b>	<b><u>Description of Document</u></b>
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	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).
4.4	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).
31.1	Certification of Chief Executive Officer pursuant to Rule 13-a-14(a) or Rule 15(d)-14(a) of the Exchange Act
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Exchange Act
32.1	Certification of Chief Executive Officer and Chief Financial 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

Cross references to other filings in the table above incorporate such agreements and descriptions above by reference here.

## CERTIFICATIONS

I, Harold Van Wart, certify that:

1. I have reviewed this Form 10-Q of CymaBay Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2016

/s/ Harold Van Wart

Harold Van Wart

Chief Executive Officer

## CERTIFICATIONS

I, Sujal Shah, certify that:

1. I have reviewed this Form 10-Q of CymaBay Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2016

/s/ Sujal Shah

Sujal Shah

Chief Financial Officer



**CERTIFICATION**

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

1. The Company’s Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2016, 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 have set their hands hereto as of November 9, 2016.

/s/ Harold Van Wart

Harold Van Wart  
Chief Executive Officer

/s/ Sujal Shah

Sujal Shah  
Chief Financial Officer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of 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.