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

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2014

OR

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

FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission File Number 001-36500

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

Delaware	**94-3103561**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
7999 Gateway Blvd, Suite 130 Newark, CA	**94560**
(Address of principal executive offices)	**(Zip Code)**

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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, 2014, there were 14,686,969 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, 2014

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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)

	September 30, 2014 (unaudited)	December 31, 2013 (Note 2)
Assets		
Current assets:		
Cash and cash equivalents	$ 16,356	$ 24,401
Marketable securities	26,270	6,843
Contract receivables	14	110
Accrued interest receivable	223	68
Prepaid expenses	1,402	364
Other current assets	134	453
Total current assets	44,399	32,239
Property and equipment, net	91	3
Other assets	159	258
Total assets	$ 44,649	$ 32,500
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,047	$ 697
Accrued liabilities	3,990	2,251
Warrant liability	8,766	6,466
Facility loan	1,193	38
Accrued interest payable	36	36
Total current liabilities	15,032	9,488
Facility loan, less current portion	3,476	4,407
Other liabilites	10	9
Total liabilities	18,518	13,904
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;14,684,788 and 9,455,064 shares issued and outstanding as of September 30, 2014 and December 31, 2013, respectively	1	1
Additional paid-in capital	394,182	367,435
Accumulated other comprehensive (loss) income	(15)	2
Accumulated deficit	(368,037)	(348,842)
Total stockholders' equity	26,131	18,596
Total liabilities and stockholders' equity	$ 44,649	$ 32,500

See accompanying notes.

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,	
	2014	2013	2014	2013
Operating expenses:				
Research and development	$ 3,848	$ 703	$ 10,546	$ 3,162
General and administrative	1,687	683	5,853	2,780
Total operating expenses	5,535	1,386	16,399	5,942
Loss from operations	(5,535)	(1,386)	(16,399)	(5,942)
Other (expense) income:				
Interest income	19	—	48	1
Interest expense	(191)	(219)	(565)	(640)
Other (expense) income, net	(254)	298	(2,279)	422
Net loss	$ (5,961)	$ (1,307)	$ (19,195)	$ (6,159)
Net (loss) income attributable to common stockholders	$ (5,961)	$ 42,870	$ (19,195)	$ 16,478
Net loss	(5,961)	(1,307)	(19,195)	(6,159)
Other comprehensive loss:				
Unrealized loss on marketable securities	(15)	—	(17)	—
Other comprehensive loss	(15)	—	(17)	—
Comprehensive loss	$ (5,976)	$ (1,307)	$ (19,212)	$ (6,159)
Basic net (loss) income per common share	$ (0.44)	$ 422.95	$ (1.72)	$ 433.33
Diluted net loss per common share	$ (0.44)	$ (1.79)	$ (1.72)	$ (8.94)
Weighted average common shares outstanding used to calculate basic net loss per common share	13,468,081	101,358	11,148,695	38,027
Weighted average common shares outstanding used to calculate diluted net loss per common share	13,468,081	731,970	11,148,695	688,825

See accompanying notes.

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

	Nine Months Ended September 30,	
	2014	2013
Operating activities		
Net loss	$(19,195)	$ (6,159)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	13	50
Amortization of notes payable conversion option	—	10
Non-employee stock-based compensation expense	5	—
Employee and director stock-based compensation expense	1,012	49
Amortization of premium on marketable securities	289	—
Non-cash interest associated with debt discount accretion	144	—
Change in fair value of warrant liability	2,289	—
Loss (gain) on sale of property and equipment	2	(425)
Changes in assets and liabilities:		
Contract receivables	96	108
Accrued interest receivable	(155)	9
Prepaid expenses	(1,038)	114
Other assets	(35)	—
Accounts payable	350	382
Accrued liabilities	2,491	310
Accrued interest payable	80	632
Other liabilities	10	(1)
Net cash used in operating activities	(13,642)	(4,921)
Investing activities		
Purchases of property and equipment	(103)	—
Proceeds from sale of property and equipment	—	450
Purchases of marketable securities	(24,782)	—
Proceeds from sales and maturities of marketable securities	5,049	—
Net cash (used in) provided by investing activities	(19,836)	450
Financing activities		
Proceeds from facility loan		4,853
Proceeds from issuance of common stock and warrants, net of issuance costs	25,430	23,975
Repurchase of preferred stock	—	(3)
Proceeds from issuance of common stock upon exercise of employee stock options	3	—
Net cash provided by financing activities	25,433	28,825
Net (decrease) increase in cash and cash equivalents	(8,045)	24,354
Cash and cash equivalents at beginning of period	24,401	7,726
Cash and cash equivalents at end of period	$ 16,356	$ 32,080
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 328	$ —
Issuance of common stock warrants-lenders	443	479
Issuance of common stock warrants-common stock	—	4,831
Conversion of preferred shares into common stock	—	323,155
Issuance of common stock for debt extinguishment	—	16,945
Issuance of common stock upon cashless warrant exercise	432	—
Noncash issuance costs incurred in common stock financing	453	—
Reclassification of incentive awards to equity	121	—

See accompanying notes.

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 metabolic diseases with high unmet medical need, including serious rare and orphan disorders. The Company's lead product candidate, arhalofenate, is being developed for the treatment of gout. The Company's second product candidate, MBX-8025, is being considered for the treatment of certain orphan diseases. 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.

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

On September 30, 2013, the Company sold shares of its common stock and warrants to purchase shares of its common stock in a private placement for aggregate gross proceeds of $26.8 million, and raised an additional $5.0 million in venture debt financing pursuant to a $10.0 million loan agreement which it entered into simultaneously with the private placement on September 30, 2013, resulting in aggregate net proceeds to the Company of $28.8 million after deducting placement agent fees and estimated offering expenses. At the same time the Company issued shares of its common stock in cancellation of approximately $16.9 million of debt owed to the holder of that debt. On October 31, 2013, the Company sold additional shares of its common stock and warrants to purchase shares of its common stock, which sales are also part of the private placement, for net proceeds of $2.2 million after deducting placement agent fees and estimated offering expenses. Further, on November 22, 2013, the Company entered into an agreement with investors to purchase shares of its common stock and warrants to purchase shares of its common stock as part of the private placement for net proceeds of $2.7 million, which sales occurred on January 29, 2014. The Company refers to the private placement, the venture debt financing and the issuance of the Company's common stock in cancellation of the $16.9 million of debt as the 2013 financing.

The Company has incurred net operating losses and negative cash flows from operations since its inception. During the nine months ended September 30, 2014, the Company incurred a loss from operations of $19.2 million and used $13.6 million of cash in operations. At September 30, 2014, the Company had an accumulated deficit of $368.0 million. CymaBay expects to incur increased research and development expenses as it continues to study its product candidates in clinical trials.

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 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, 2013, which is contained in the Company's Annual Report on Form 10-K as filed with the SEC on March 31, 2014. The results for the nine months ended September 30, 2014, are not necessarily indicative of results to be expected for the year or for any other period.

Use of Estimates

The 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 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 liabilities, and equity and liability instrument valuations.

Reverse Stock Split

On September 30, 2013, the Company filed an amended and restated certificate of incorporation under which the Company's preferred stock and common stock was reverse split on a 1-for-79.5 basis. The accompanying financial statements and notes to the financial statements, give retroactive effect to the reverse split for all periods presented.

Fair Value of Financial Instruments

The Company's financial instruments during the periods reported consist of cash and cash equivalents, contract receivables, short-term marketable securities, accounts payable, accrued expenses, warrant liabilities and convertible notes. 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 and therefore cannot be determined with precision.

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. Assets and liabilities that are measured at fair value are reported using a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. This hierarchy maximizes the use of observable inputs and maximizes the use of unobservable inputs and is as follows:

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

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

Level 3—Inputs that are unobservable for the asset or liability.

The carrying amounts of financial instruments such as cash and cash equivalents, contract receivables, accounts payable and accrued expenses approximate the related fair values due to the short-term maturities of these instruments.

	As of September 30, 2014 (In thousands)			
Description	**Level 1**	**Level 2**	**Level 3**	**Fair Value**
Money market funds	$15,275	$ —	$ —	$ 15,275
Corporate debt and asset backed securities	—	26,270	—	26,270
Total assets measured at fair value	$15,275	$26,270	$ —	$ 41,545
Warrant liability	$ —	$ —	$8,766	$ 8,766
Total liabilities measured at fair value	$ —	$ —	$8,766	$ 8,766

Marketable securities consist of available-for-sale securities that are reported at fair value, with the related unrealized gains and losses included in accumulated other comprehensive income (loss), a component of stockholders' equity. The Company values cash equivalents and marketable securities using quoted market prices or alternative pricing sources and models utilizing observable market inputs and, as such, classifies cash equivalents and marketable securities within Level 1 or Level 2.

The Company holds a Level 3 liability associated with common stock warrants that were issued in connection with the Company's 2013 financing. The warrants are considered a liability and are valued using an option-pricing model, the inputs for which include the exercise price of the warrants, market price of the underlying common shares, expected term, volatility based on a group of the Company's peers and the risk-free rate corresponding to the expected term of the warrants. As of December 31, 2013, the Company also held a Level 3 liability associated with a forward contract which arose in connection with the Company's November 22, 2013 execution of an equity purchase agreement with certain investors. The agreement required the Company to issue a fixed number of shares of common stock and warrants to purchase common stock at a predetermined price of $3.0 million provided the Company completes the listing of its common stock on a public stock exchange. The forward contract's fair value was determined upon execution as the difference between the present value of the equity proceeds to be received under the agreement less the fair value of the underlying securities. The forward contract liability was presented in the balance sheet as a component of accrued liabilities and was revalued at each reporting period until contract settlement which occurred on January 29, 2014. The fair value of the underlying common stock and warrants were valued using an option-pricing model, the inputs of which are similar to those used in the valuation of the Company's liability classified warrants. Changes to any of the inputs to the option-pricing models used by the Company can have a significant impact to the estimated fair value of the warrants and forward contract liabilities.

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):

	Warrant Liability	Forward Contract
Balance as of December 31, 2013	$ 6,466	$ 453
Issuance of financial instrument	443	—
Change in fair value	2,289	(10)
Settlement of financial instrument	(432)	(443)
Balance as of September 30, 2014	$ 8,766	$ —

The gains and losses from remeasurement of Level 3 financial liabilities are recorded through other income (expense), net on the accompanying statements of operations and comprehensive loss.

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 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 balance sheet.

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 income (loss), in the balance sheet. 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.

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, 2014 and December 31, 2013, cash restricted under these arrangements was $100,000 and $155,000, respectively. These amounts are 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 balance sheet. The Company invests cash that is not required for immediate operating needs primarily in highly liquid instruments that bear minimal risk. The Company has established guidelines relating to the quality, diversification, and maturities of securities to enable the Company to manage its credit risk.

Property and Equipment

Property and equipment is stated at cost, less accumulated depreciation and amortization. Depreciation and amortization is calculated using the straight-line method, and the cost is amortized over the estimated useful lives of the respective assets, generally three to seven years. Leasehold improvements are amortized over the shorter of the useful lives or the non-cancelable term of the related lease. Maintenance and repair costs are charged as expense in the statements of operations and comprehensive income (loss) as incurred.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss is recognized if the estimated undiscounted future cash flow expected to result from the use and eventual disposition of an asset is less than the carrying amount. While the Company's current and historical operating losses and cash flows are indicators of impairment, the Company believes the future cash flows to be received support the carrying value of its long-lived assets. Accordingly, the Company has not recognized any impairment losses as of September 30, 2014 and December 31, 2013.

Deferred Rent

The Company records its costs under facility operating lease agreements as rent expense. Rent expense is recognized on a straight-line basis over the non-cancelable term of the operating lease. The difference between the actual amounts paid and amounts recorded as rent expense is recorded to deferred rent in the balance sheet.

Common Stock Warrant Liability

Warrants issued to common stock holders and lenders by the Company in conjunction with the 2013 financing were classified as liabilities in the accompanying condensed balance sheets, as the terms for redemption of the underlying security were outside the Company's control. The warrants were recorded at fair value using either the Black-Scholes option pricing model, probability weighted expected return model or a binomial model, depending on the characteristics of the warrants. The fair value of these warrants is re-measured at each financial reporting period 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 based measurements of the stock 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 based measurements of options using the Black-Scholes valuation model and recognizes expense using the straight-line attribution method.

Equity awards granted to non-employees are accounted for using the Black-Scholes valuation model to determine the fair value of such instruments. The fair value of equity awards granted to non-employees are re-measured over the related vesting period and amortized to expense as earned.

Income Taxes

The Company utilizes the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and the tax bases of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is recorded when it is more likely than not that all or part of a deferred tax asset will not be realized.

The accounting guidance for uncertainty in income taxes prescribes a recognition threshold and measurement attribute criteria for the financial recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination based on the technical merits of the position. The Company records interest related to income taxes, if any, as interest, and any penalties would be recorded as other expense in the statements of comprehensive income (loss). There was no interest or penalties related to income taxes recorded during the three and nine months ended September 30, 2014 and 2013.

Comprehensive Loss

Comprehensive loss includes net loss and net unrealized gains and losses on marketable securities, which are presented in a single continuous statement. Accumulated other comprehensive income (loss) is disclosed in the condensed balance sheets, and is stated net of related tax effects, if any.

Net Loss Per Common Share

Basic net loss per share of common stock is based on the weighted average number of shares of common stock outstanding equivalents during the period. Prior to the 2013 financing, in addition to common stock, the Company had preferred stock outstanding that contractually entitled the holder to participate in dividends and earnings of the Company. Accordingly, the Company applied the two-class method for calculating net loss per share. Under this method, all undistributed earnings are allocated first to the preferred stockholders based on their contractual right to dividends. This right is calculated on a pro rated basis for the portion of the period the preferred shares were outstanding. On September 30, 2013, in connection with the 2013 financing, all outstanding shares of the Company's preferred stock were converted into shares of the Company's common stock. Accordingly, no preferred stock was outstanding during the three and nine months ended September 30, 2014.

Diluted net loss per share of common stock is calculated using the more dilutive of the two approaches: one, "as-converted" method, under which the weighted average number of common stock shares outstanding during the period is adjusted to include the assumed conversion of redeemable convertible preferred stock at the beginning of the period, and the other, the "two-class" method as described above. Under either approach, the weighted average number of shares outstanding is also 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Basic:				
Numerator:				
Net loss	$ (5,961)	$ (1,307)	$ (19,195)	$ (6,159)
Accretion to redemption value of redeemable convertible preferred stock	—	(3,036)	—	(9,289)
Reduction in redeemable convertible preferred stock distribution entitlement upon extinguishment	—	313,933	—	313,933
Amounts allocated to participating redeemable convertible preferred stock	—	(266,720)	—	(282,007)
Net (loss) income allocated to common stock—basic	$ (5,961)	$ 42,870	$ (19,195)	$ 16,478
Denominator:				
Weighted average number of common stock shares outstanding—basic	13,468,081	101,358	11,148,695	38,027
Net (loss) income per share-basic:	$ (0.44)	$ 422.95	$ (1.72)	$ 433.33
Diluted:				
Numerator:				
Net (loss) income allocated to common stock	$ (5,961)	$ 42,870	$ (19,195)	$ 16,478
Adjustments from assumed conversion of redeemable convertible preferred stock	—	(44,177)	—	(22,637)
Net loss allocated to common stock—diluted	$ (5,961)	$ (1,307)	$ (19,195)	$ (6,159)
Denominator:				
Weighted average number of common stock shares outstanding	13,468,081	101,358	11,148,695	38,027
Weighted average number of preferred stock shares outstanding	—	630,612	—	650,798
Total common stock equivalent shares	13,468,081	731,970	11,148,695	688,825
Net loss per share—diluted	$ (0.44)	$ (1.79)	$ (1.72)	$ (8.94)

The following table shows the total outstanding securities considered anti-dilutive and therefore excluded from the computation of diluted net loss per share.

	Three and Nine Months Ended September 30,	
	2014	2013
	(unaudited)	
Warrants for common stock	1,787,617	1,543,437
Common stock options	992,033	89,609
Incentive awards	247,515	—
	3,027,165	1,633,046

3. Certain Balance Sheet Items

Property and equipment consists of the following (in thousands):

	September 30, 2014 (unaudited)	December 31, 2013
Office and computer equipment	$ 176	$ 556
Purchased software	46	166
Furniture and fixtures	33	42
Leasehold improvements	66	2,534
Total	321	3,298
Less accumulated depreciation and amortization	(230)	(3,295)
Property and equipment, net	$ 91	$ 3

In March 2014, the Company ceased use of a substantial portion of its leased facility in Hayward, California. In connection with the closure of this facility, the Company disposed of certain fully depreciated leasehold improvements. In June 2014, the Company completed a physical inventory of its property and equipment and disposed of certain fully depreciated computers, equipment and software.

Accrued liabilities consist of the following (in thousands):

	September 30, 2014 (unaudited)	December 31, 2013
Accrued compensation	$ 842	$ 518
Accrued pre-clinical and clinical trial expenses	2,815	418
Accrued professional fees	242	782
Forward contract	—	453
Other accruals	91	80
Total accrued liabilities	$ 3,990	$ 2,251

4. Common Stock Warrants

In January 2014, in connection with the 2013 financing, the Company completed the sale of common stock for aggregate proceeds of $3.0 million and as part of this transaction, the Company issued five-year warrants to purchase 120,800 shares of common stock at an exercise price of $5.75 per share. Due to certain provisions, the Company is required to account for the warrants issued as a liability at fair value. In addition, the estimated liability related to the warrants is required to be revalued at each reporting period until the earlier of the exercise of the warrants, at which time the liability will be reclassified to stockholders' equity, or expiration of the warrants. At issuance date, the fair value of the total warrant liability was estimated to be $0.4 million using a binomial lattice options-pricing model.

5. Collaboration and License Agreements

In August 2006, CymaBay entered into a strategic alliance with Ortho-McNeil, Inc., a subsidiary of Johnson and Johnson. As part of the alliance, Janssen Pharmaceutical NV, an affiliate of Ortho-McNeil, granted to CymaBay an exclusive worldwide, royalty-bearing license to MBX-8025 and certain other PPARδ compounds (the "PPARδ Products") with the right to grant sublicenses to third parties to make, use and sell such PPARδ Products. Under the terms of the agreement, CymaBay has full control and responsibility over the research, development and registration of any PPARδ Products and is required to use diligent efforts to conduct all such activities. Janssen has the sole responsibility for the preparation, filing, prosecution, maintenance of, and defense of the patents with respect to, the PPARδ Products. Janssen has a right of first negotiation under the agreement to license a particular PPARδ Product from CymaBay in the event that CymaBay elects to seek a third party corporate partner for the research, development, promotion, and/or commercialization of such PPARδ Products. Under the terms of the agreement Janssen is entitled to receive up to an 8% royalty on net sales of PPARδ Products. No payments were made and no royalties were received under this agreement during the three and nine months ended September 30, 2014 and 2013.

In June 2010, CymaBay 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. CymaBay is also eligible to receive up to $228 million in contingent payments if certain development and commercial events are achieved as well as royalties on worldwide net sales of products. No such payments have been made to date. Under the terms of the agreements, Janssen has full control and responsibility over the research, development and registration of any products developed and/or discovered from the metabolic disease targets and is required to use diligent efforts to conduct all such activities.

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. Pursuant to the license agreement, all of the Company's patents and patent applications related to arhalofenate, its use, and production are jointly owned with DiaTex. DiaTex is entitled to up to $0.8 million for the future development of arhalofenate, as well as a 2% royalty payment on net sales of products containing arhalofenate. No development payments were made in the three and nine months ended September 30, 2014 and 2013, and no royalties have been paid to date.

6. Debt

On June 20, 2006 the Company entered into an equity and loan facility with the Johnson and Johnson Development Corporation ("JJDC") pursuant to which the Company could drawn down up to an aggregate of $30 million in loans in the form of convertible preferred stock promissory notes. In March and September 2008, the Company issued notes in the aggregate amount of $3.5 million and $10.5 million, respectively. The notes were due on March 17 and September 17, 2011, including interest that accrued at 7.57% per annum. In December 2010, the aggregate principal amount and all accrued interest under the notes issued in March and September 2008 were converted into the Company's Series E-3 convertible preferred stock (Series E-3 Preferred) at $232.93 per share.

In February and July 2009, the Company issued notes in the aggregate amount of $7.0 million and $6.7 million, respectively, which represented the remaining amount available to the Company, in accordance with the terms of the equity and loan facility with JJDC. The notes were due in February 2012 and July 2012, including interest that accrued at 4.42% per annum and 4.960% per annum, respectively. In January 2012, the Company amended the maturity dates of the outstanding $7.0 million and $6.7 million convertible promissory notes to extend the maturity date to March 1, 2013, and interest rates were increased to 4.919% and 5.46% per annum, respectively. In addition, the conversion price of the notes to convert into shares of the Company's Series C-1 Preferred Stock was decreased from $438.84 per share to $292.56 per share. All of these notes were further amended in March 2013, to extend the maturity date on the notes to August 1, 2013, and to make the notes subordinate to repayment of the Company's severance obligations to all employees until January 1, 2014. On July 31, 2013, the maturity date was extended to December 31, 2013. There were no financial covenants associated with the notes. For the three and nine months ended September 30, 2013, the Company recognized $0.2 million and $0.6 million, respectively, of interest expense related to the convertible promissory notes. On September 30, 2013, the outstanding principal and accrued interest of $16.9 million under the equity and loan facility with JJDC was extinguished in exchange for 624,944 shares of common stock as an integral part of the 2013 financing.

Facility Loan

On September 30, 2013, the Company entered into a facility loan agreement with Silicon Valley Bank and Oxford Finance for a total loan amount of $10.0 million of which the first tranche of $5.0 million was drawn as part of the 2013 financing. The loan has 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. Until positive Phase 2b data is achieved, the Company must be in compliance with one of two financial covenants at all times: (1) maintain 1.3 times cash to outstanding debt or (2) maintain sufficient cash on hand to support eight months of operations based on a trailing average monthly cash burn. As of September 30, 2014, the Company was in compliance with both financial covenants. The first tranche loan under the term loan facility bears interest at a rate equal 8.75% per annum. Loans under the second tranche will bear interest at a rate fixed at the time of borrowing equal to the greater of (i) 8.75% per annum and (ii) the sum of the Wall Street Journal prime rate plus 4.25% per annum. The Company was also required to pay a facility fee of 1.00% on the term loan facility commitment.

At the time of the facility loan drawdown, 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. As a result of this issuance, a warrant liability of $0.5 million was recorded in the accompanying condensed balance sheets and it must be revalued at each balance sheet date.

7. Commitments and Contingencies

The Company leased office and laboratory space in a single building in Hayward, California. The facility lease, as amended on July 15, 2010, had a term of four years and expired on April 30, 2014. On November 8, 2013, the Company entered into a new lease commencing January 16, 2014, and expiring on December 31, 2018, for 8,894 square feet of office space in Newark, California. Rent expense was $0.1 million for each of the three months ended September 30, 2014 and 2013.

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

	Lease Payments
Year ending December 31:	
2014 (remaining 3 months)	$ 51
2015	209
2016	216
2017	222
2018	228
Total future minimum payments	$ 926

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 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 has not recognized any liabilities relating to these obligations as of September 30, 2014 and December 31, 2013. 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

Upon the closing in the 2013 financing on September 30, 2013, all of the outstanding shares of redeemable convertible preferred stock of the Company were converted into 2,793,281 shares of common stock, and the related carrying value of $320.0 million was reclassified to additional paid-in capital. As of September 30, 2014, no shares of redeemable convertible preferred stock were issued or outstanding.

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, 2014.

On September 30, 2013, the Company sold 5,366,669 shares of common stock and 1,073,338 warrants to purchase shares of common stock in the 2013 financing for net proceeds to the Company of $22.8 million after deducting placement agent fees and estimated offering expenses. Also on that date, the Company issued 624,944 shares of common stock in cancellation of approximately $16.9 million of debt owed to JJDC, the holder of that debt (Note 6). On October 31, 2013, the Company sold an additional 664,300 shares of common stock and warrants to purchase 132,860 shares of common stock, which sales were also part of the 2013 financing,

for net proceeds to CymaBay of $2.2 million after deducting placement agent fees and estimated offering expenses. On November 22, 2013, the Company entered into an agreement with investors to purchase 604,000 shares of common stock and 120,800 warrants to purchase shares of common stock as part of the 2013 financing for net proceeds of $2.7 million, which sales occurred on January 2014.

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

As of September 30, 2014 and December 31, 2013, the Company had reserved shares of authorized but unissued common stock as follows:

	September 30, 2014 (unaudited)	December 31, 2013
Common stock warrants	1,787,617	1,742,727
Equity incentive plans	1,549,716	577,294
Total reserved shares of common stock	3,337,333	2,320,021

9. Stock Plans and Stock-Based Compensation

Stock Plans

On September 30, 2013, the Company's stockholders approved the 2013 Equity Incentive Plan, or 2013 Plan, under which shares of the Company's common stock are reserved for issuance pursuant to stock awards, including, but not limited to, incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards, and performance cash awards. In addition, the share reserve automatically increased by 472,753 shares on January 1, 2014, and will continue to automatically increase on January 1st of each year, for a period of not more than ten years, in an amount equal to 5% of the total number of shares of capital stock outstanding on December 31st of the preceding calendar year, unless the Board determines otherwise prior to December 31st of such calendar year. In June 2014, the Company's stockholders approved a proposal to increase the share reserve by an additional 500,000 shares. From plan inception through September 30, 2014, the Company had issued options for an aggregate of 933,647 shares of the Company's common stock under the 2013 Plan.

Stock-Based Compensation Expense

Employee and Director Expense

Employee and director stock-based compensation expense recorded was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
	(unaudited)		(unaudited)	
Research and development	$ 73	$ 5	$ 256	$ 16
General and administrative	152	11	761	33
Total	$ 225	$ 16	$ 1,017	$ 49

On June 3, 2014, stockholders approved a proposal to increase the Company's stock option plan share reserve with sufficient shares to enable the Company to share settle certain incentive awards previously issued to the Company's employees and directors. Prior to the share reserve increase the Company could only cash settle the incentive awards and therefore these awards were required to be revalued at each reporting date and presented as liabilities on the condensed balance sheet. On June 3, 2014, the incentive awards became equity classified for accounting purposes and accordingly, the Company revalued the awards and reclassified $0.1 million from accrued liabilities to additional paid in capital.

10. Related-Party Transactions

The Company paid a former member of its Board of Directors, who is also a member of its Scientific and Clinical Advisory Boards, a total of $45,000 in the year ended December 31, 2013 and $40,000 for the nine months ended September 30, 2014, in monthly cash retainers. The Company also issued options to purchase shares of common stock and incentive awards to this individual in his capacity as a member of its Scientific Advisory Board.

11. Subsequent Events

On November 7, 2014, the Company filed a $100 million registration statement on Form S-3 with the SEC and also entered into an at-the-market facility (ATM) to sell up to $25 million of common stock under the registration statement.

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, 2014, 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," "should," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "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 a biopharmaceutical company focused on developing therapies to treat metabolic diseases with high unmet medical need, including serious rare and orphan disorders. Our lead product candidate, arhalofenate, is being developed for the treatment of gout. CymaBay has completed three Phase 2 studies of arhalofenate in gout patients in which it demonstrated a consistent pattern of reduction of flare incidence and duration and lowering of serum uric acid (sUA). One additional Phase 2b clinical study of 12 weeks duration is ongoing to confirm the safety and efficacy of a higher dose prior to initiating Phase 3 studies. Our second product candidate, MBX-8025, demonstrated favorable effects on cholesterol, triglycerides and markers of liver health in a Phase 2 clinical trial in patients with mixed dyslipidemia. We are considering pursuing MBX-8025 in a number of orphan diseases in which these attributes would be beneficial, such as Homozygous Familial Hypercholestorolemia (HoFH), severe hypertriglyceridemia (SHTG) and primary biliary cirrhosis (PBC).

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".

Reverse Stock Split

On September 30, 2013, we effected a 1-for-79.5 reverse split of our preferred stock and common stock, which we refer to as the reverse stock split, The discussion in this "Management's Discussion and Analysis of Financial Conditions and Results of Operations" gives retroactive effect to the reverse stock split.

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. Actual results may materially differ from these estimates under different assumptions or conditions.

We discussed accounting policies and assumptions that involve a higher degree of judgment and complexity within Note 2 to our audited financial statements in our Annual Report on Form 10-K filed with the SEC on March 31, 2014. There were no material changes to our critical accounting policies and estimates during the nine months ended September 30, 2014.

Results of Operations

General

To date, we have not generated any income from operations. Since our date of incorporation through September 30, 2014, we have an accumulated deficit of $368.0 million, primarily as a result of expenditures for research and development and general and administrative expenses. 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.

	Three Months Ended September 30,			Nine Months Ended September 30,		
($ in thousands)	2014	2013	Variance	2014	2013	Variance
Operating expenses:						
Research and development	$ 3,848	$ 703	$ 3,145	$ 10,546	$ 3,162	$ 7,384
General and administrative	1,687	683	1,004	5,853	2,780	3,073
Loss from operations	(5,535)	(1,386)	(4,149)	(16,399)	(5,942)	(10,457)
Interest expense, net	(172)	(219)	47	(517)	(639)	122
Other (expense) income, net	(254)	298	(552)	(2,279)	422	(2,701)
Net loss	$ (5,961)	$ (1,307)	$(4,654)	$(19,195)	$(6,159)	$(13,036)

Research & Development Expenses

Conducting research and development is central to our business model. For the three months ended September 30, 2014 and 2013, research and development expenses were $3.8 million and $0.7 million, respectively. For the nine months ended September 30, 2014 and 2013, research and development expenses were $10.5 million and $3.2 million respectively. Research and development expenses are detailed in the table below:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
($ in thousands)	(unaudited)		(unaudited)	
Arhalofenate - Phase 2b Randomized Study	$ 1,974	$ 68	$ 6,096	$ 82
Arhalofenate - Febuxostat Combo Study	347	—	376	—
Arhalofenate Gout – Drug manufacturing	504	67	981	590
Arhalofenate Gout – Three Phase 2 Randomized Studies	(1)	(14)	(90)	9
MBX-8025	118	—	225	—
Other Projects	11	12	27	57
Total Project Costs	2,953	133	7,615	738
Internal Research and Development Costs	895	570	2,931	2,424
Total Research and Development	$ 3,848	$ 703	$10,546	$3,162

Our external research and development 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, lab supplies and overhead expenses. Internal costs generally benefit multiple projects and are not separately tracked per project.

Total project costs increased by $2.8 million during the three months ended September 30, 2014 as compared to the three months ended September 30, 2013, due to ongoing clinical trial activities for arhalofenate, our lead product candidate. Specifically, substantial costs were incurred for clinical research services performed by our CRO partner to coordinate patient dosing visits at investigator sites, patient sample testing, data collection and analysis, and other clinical trial activities. Internal research and development cost increased by $0.3 million for the three months ended September 30, 2014 as compared to the three months ended September 30, 2013 due to increased employee compensation expenses and consulting services incurred in 2014 primarily to support the expansion of our clinical development activities for arhalofenate.

Total project costs increased by $6.9 million during the nine months ended September 30, 2014 as compared to the nine months ended September 30, 2013, due to ongoing clinical trial activities for arhalofenate, our lead product candidate. Specifically, substantial costs were incurred for clinical research services performed by our CRO partner to coordinate patient dosing visits at investigator sites, sample testing, data collection and analysis, and other clinical trial activities. Internal research and development increased $0.5 million for the nine months ended September 30, 2014 as compared to the nine months ended September 30, 2013 due to increased employee compensation expenses and consulting services incurred in 2014 primarily to support the expansion of our clinical development activities for arhalofenate.

We expect to continue to incur substantial expenses related to our development activities for the foreseeable future as we continue product development for arhalofenate and initiate our next clinical studies for MBX-8025. 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 increased $1.0 million for the three months ended September 30, 2014 as compared to the three months ended September 30, 2013 due primarily to an increase in headcount related expenses and an increase in professional fees and compliance costs associated with operating as a public company.

General and administrative expenses increased $3.1 million for the nine months ended September 30, 2014 as compared to the nine months ended September 30, 2013 due primarily to an increase of $1.1 million in headcount related expenses, an increase of $1.0 million in professional fees and compliance costs associated with operating as a public company, and an increase of $0.7 million for employee and director stock-based compensation expense.

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 (Expense) Income, Net

Other (expense) income, net for the three and nine months ended September 30, 2014 reflected a loss of $0.3 million and a loss of $2.3 million, respectively, due to the remeasurement of our warrant liabilities at fair value as of September 30, 2014. We use a binomial lattice option pricing model to value our warrants at each reporting date and the warrant valuations changed due to variations in the price of our common stock which is an input to our valuation model. Specifically, during the three months ended September 30, 2014, the loss recognized was due primarily to an increase in the value of our common stock from $6.50 at June 30, 2014 to $6.84 at September 30, 2014. During the nine months ended September 30, 2014, the loss recognized was due primarily to an increase in the value of our common stock from $5.00 at December 31, 2013 to $6.84 at September 30, 2014. No warrants subject to liability accounting were outstanding during the three and nine month periods ended September 30, 2013.

Liquidity and Capital Resources

To date, we have funded our operations through the sale of equity securities, licensing fees, issuance of debt and collaborations with third parties. At September 30, 2014, we had cash, cash equivalents and marketable securities of $42.6 million, primarily as a result of the aggregate proceeds received in a series of equity and debt transactions initiated in 2013 and completed in 2014.

Specifically, on September 30, 2013, all of the shares of our outstanding redeemable convertible preferred stock converted to common stock, we sold shares of our common stock and warrants to purchase shares of our common stock in a private placement for aggregate gross proceeds of $26.8 million, and raised an additional $5.0 million in venture debt financing pursuant to a $10.0 million loan agreement which we entered into simultaneously with the private placement, resulting in aggregate net proceeds to us of $28.8 million after deducting placement agent fees and offering expenses. At the same time we issued shares of our common stock in cancellation of approximately $16.9 million of debt owed to the holder of that debt.

On October 31, 2013, we sold additional shares of our common stock and warrants to purchase shares of our common stock, which sales are also part of the private placement, for net proceeds to us of $2.2 million after deducting placement agent fees and offering expenses.

Further, on November 22, 2013, we entered into an agreement with investors to purchase shares of our common stock and warrants to purchase shares of our common stock for net proceeds of $2.7 million, which sales occurred on January 29, 2014. We refer to the private placement, the venture debt financing and the issuance of our common stock in cancellation of the $16.9 million of debt as the 2013 financing.

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.

Term Loan Facility

The venture debt financing referenced in the 2013 financing was provided to us pursuant to a term loan facility with Silicon Valley Bank and Oxford Finance LLC, collectively referred to as the lenders, for an aggregate amount of $10 million, $5 million of which was made available to us as of September 30, 2013, and the remaining $5 million, referred to as the second tranche, which shall be made available to us upon the achievement of positive data and successful completion of all primary endpoints for either the 600 mg or 800 mg dose of arhalofenate in our planned Phase 2b study (the “second draw milestone”). The second tranche shall be available to us until the earlier of June 30, 2015, or the occurrence and continuation of an event of default (as described in the term loan facility). Each tranche matures 48 months following the funding date of such tranche. The proceeds of the term loan facility may be used for general corporate purposes.

The first tranche loans under the term loan facility bear interest at a rate equal 8.75% per annum. Loans under the second tranche will bear interest at a rate fixed at the time of borrowing equal to the greater of (i) 8.75% per annum and (ii) the sum of the Wall Street Journal prime rate plus 4.25% per annum. We were also required to pay a facility fee of 1.00% on the term loan facility commitment.

We are permitted to make voluntary prepayments of the term loans with a prepayment fee equal to 3% of the term loans prepaid. On each 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 the outstanding principal of the outstanding term loans of each tranche. After the 36-month amortization period of each tranche, the remaining balance of such tranche and a final payment equal to 6.50% of the original principal amount of the applicable tranche are payable on the maturity date of such tranche. 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 (each as defined or described under the term loan facility) 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, (1) by a first priority pledge of all of the equity interests of each of our direct and indirect subsidiaries, and (2) a perfected first priority interest in all of our tangible and intangible assets, including all of our intellectual property.

The term loan facility contains customary representations and warranties and customary affirmative and negative covenants applicable to us and our subsidiaries, 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. Until the occurrence of the second draw milestone, the term loan facility contains financial covenants that require us to maintain a certain cash liquidity. The term loan facility also contains performance covenants that require that: (a) within one hundred twenty (120) days of us becoming eligible to file a registration statement with the United States Securities and Exchange Commission on Form S-3, we must have access to an At The Market facility; and (b) by no later than March 31, 2015, the lenders must have received evidence of the occurrence of the second draw milestone; provided that our failure to comply with these performance covenants shall not be an event of default under the term loan facility so long as we deposit an amount equal to 100% of the aggregate outstanding term loans in a segregated, blocked deposit account at Silicon Valley Bank.

The 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, cross-defaults on our or any our subsidiary's material indebtedness, bankruptcy, material judgments and misrepresentations. Upon an event of default, the lenders may, among other things, accelerate the loans and foreclose on the collateral.

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,	
	2014	2013
Net cash used in operating activities	$(13,642)	$ (4,921)
Net cash (used in) provided by investing activities	(19,836)	450
Net cash provided by financing activities	25,433	28,825
Net (decrease) increase in cash and cash equivalents	$ (8,045)	$24,354

Operating Activities: Net cash used in operating activities for the nine months ended September 30, 2014 was $13.6 million and was primarily due to a net loss of $19.2 million resulting from ongoing clinical trial activities for arhaolfenate, our lead product candidate. This net loss was partially offset by a $2.3 million noncash adjustment to revalue our warrant liability, $1.0 million of stock-based compensation, and other changes in working capital due primarily to prepayments made and accrued expenses incurred in connection with our clinical trial activities.

Investing Activities: Net cash used in investing activities was $19.8 million for the nine months ended September 30, 2014 and was primarily due to the net purchase of marketable securities.

Financing Activities: Cash provided by financing activities was $25.4 million for the nine months ended September 30, 2014, primarily as a result of $23.0 million in net proceeds received from a July 2014 public offering of our common stock and $2.4 million in net proceeds received upon consummation of an agreement with investors to purchase shares of our common stock and warrants to purchase shares of our common stock in January 2014 as part of the 2013 financing.

Management believes that cash, cash equivalents and marketable securities held as of September 30, 2014 are sufficient to sustain our operations through the fourth quarter of 2015. We expect to incur substantial expenditures in the foreseeable future for the development and potential commercialization of our product candidates. We will continue to require additional financing to develop our products and fund operating losses. We will seek funds through equity financings, debt, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate additional funding may not be available to us on acceptable 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 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, 2013 as filed with the SEC on March 31, 2014.

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 not effective at the reasonable assurance level because of a material weakness in our internal control over financial reporting, as described below.

(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 not effective at the reasonable assurance level because of a material weakness in our internal control over financial reporting, as described below.

(c) *Changes in Internal Controls*. There were no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2014, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, except as described below.

In connection with the preparation of our financial statements for the three and six months ended June 30, 2014, we determined that we had a material weakness in our internal control over financial reporting because we did not adequately perform a review of a draft valuation report used to calculate our aggregate warrant liabilities. If left unadjusted by management, our outstanding warrant liability and our reported net loss would have been misstated by $1.2 million. The error in the valuation service report was not detected until we received the final valuation report where the error was corrected and management did not detect the change in the final report. The change was first recognized and brought to our attention by our independent registered public accounting firm.

We have concluded that this deficiency in the operation of our review control over the warrant liability valuation and calculation in our financial statements represents a “material weakness” in our internal control over financial reporting, and accordingly, our internal control over financial reporting was ineffective at June 30, 2014.

A material weakness is a deficiency, or a combination of deficiencies, in internal controls over financial reporting, such that there is a reasonable possibility that a material misstatement of a company’s annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

(d) *Remediation.* We have developed, and are currently implementing, a remediation plan for this material weakness. We will continue to execute our remediation plan, which includes, among other things, a secondary independent review of the warrant input values in the valuation report, and enhancing our budget versus actual variance analysis to complement our review of our financial statements in an effort to detect and address variance anomalies.

Notwithstanding our material weakness, we have concluded that the financial statements and other financial information included in this Quarterly Report on Form 10-Q, fairly present in all material respects our financial condition, results of operations and cash flows as of, and for, the periods presented.

PART II. OTHER INFORMATION

Item 1A. Risk Factors

In evaluating our business, you should carefully consider the following risks, as well as the other information contained in this Quarterly Report on Form 10-Q. These risk factors could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report on Form 10-Q and those we may make from time to time. If any of the following risks actually occurs, our business, financial condition and operating results could be harmed. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us, or that we currently see as immaterial, may also harm our business. The risks facing our business have not changed substantively from those discussed in our Annual Report on Form 10-K for the year ended December 31, 2013, except for those risk factors below designated by an asterisk (*).

Risks Related to Our Financial Condition and Capital Requirements

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

We have consumed substantial amounts of capital to date as we continue our research and development activities, including our Phase 2b study of arhalofenate. As of September 30, 2014, we had cash, cash equivalents and marketable securities of approximately $42.6 million. These funds were obtained through recent equity and debt financings including approximately $28.8 million which we raised in aggregate net proceeds on September 30, 2013, $2.2 million of additional net proceeds which we raised on October 31, 2013, $2.7 million of additional net proceeds which we raised on January 29, 2014, and $23.0 million in net proceeds received from a public offering of our common stock in July 2014. After giving effect to these financings, we believe that our existing cash will allow us to continue operation through the fourth quarter of 2015. We currently believe that we will need to raise additional capital to continue our operations beyond the fourth quarter of 2015. 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 candidate, arhalofenate, for the prevention of gout flares and the treatment of hyperuricemia in patients with gout.

In the event we do not successfully raise sufficient funds in financing our product development activities, particularly related to the ongoing development of arhalofenate and planned development of MBX-8025, 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 Phase 2b study of arhalofenate in patients with gout 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 arhalofenate, outlicense intellectual property rights to 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 planned proof-of-concept studies of MBX-8025;
- the need for additional or expanded clinical studies;
- the rate of progress and cost of our Chemistry, Manufacturing and Control registration and validation program;
- the timing, economic and other terms of any licensing, collaboration or other similar arrangement into which we may enter;
- the costs and timing of seeking and obtaining 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 losses since our inception. We anticipate that we will continue to incur significant losses for the foreseeable future, and we may never achieve or maintain profitability.*

We are a biopharmaceutical company focused primarily on developing our lead product candidate, arhalofenate. We have incurred significant net losses in each year since our inception, including a net loss of approximately $10.1 million for the year ended December 31, 2013, and a net loss of $19.2 million for the nine months ended September 30, 2014. As of September 30, 2014, we had an accumulated deficit of $368.0 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 lead product candidate, arhalofenate, for the prevention of flares and treatment of hyperuricemia in patients with gout;
- 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;
- expand our research and development activities and advance our clinical programs, including MBX-8025;
- 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 arhalofenate or future product candidates may be reduced in scope, delayed or terminated. If our product candidates or those of its collaborators 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.

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

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

- obtaining favorable results for and advancing the development of arhalofenate, including successfully initiating and completing our Phase 2b and Phase 3 clinical development;
- obtaining United States (U.S.) and foreign regulatory approvals for arhalofenate;
- launching and commercializing arhalofenate, either on our own or with a partner, including building a sales force and collaborating with third parties;
- achieving broad market acceptance of arhalofenate in the medical community and by third-party payors and patients;
- obtaining favorable results for and advancing the development of MBX-8025; and
- generating a pipeline of product candidates.

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

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

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. We do not have any committed external source of funds.

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

If we raise additional funds through collaborations, strategic alliances, or licensing arrangements or other marketing or distribution arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to expand our operations or otherwise capitalize on our business opportunities, our business, financial condition and results of operations could be materially adversely affected and we may not be able to meet our debt service obligations. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts, or grant others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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

We are an emerging growth company. Under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We plan to avail ourselves of 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.”

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

We will remain an emerging growth company until the earliest of (i) the end of the fiscal year in which the market value of our common stock that is held by non-affiliates exceeds $700 million as of the end of the second fiscal quarter, (ii) the end of the fiscal year in which we have total annual gross revenues of $1 billion or more during such fiscal year, (iii) the date on which we issue more than $1 billion in non-convertible debt in a three-year period or (iv) the end of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement filed under the Securities Act.

Risks Related to Clinical Development and Regulatory Approval

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

We have not marketed, distributed or sold any products. The success of our business depends upon our ability to develop and commercialize our lead product candidate, arhalofenate, which has completed eight Phase 1 and seven Phase 2 clinical trials, including three Phase 2 studies in gout and our second product candidate, MBX-8025, which has completed five Phase 1 and one Phase 2 clinical trials. We are conducting a Phase 2b clinical trial for arhalofenate in preventing flares and reducing serum uric acid in gout patients prior to initiation of a Phase 3 program. We are also conducting a Phase 2 study in gout patients of arhalofenate in combination with febuxostat to examine the effects on serum uric acid and the potential for its interaction with febuxostat. There is no guarantee that our clinical trials will be completed or, if completed, will be successful. For example, the 800 mg dose of arhalofenate used in our Phase 2b gout trial and our Phase 2 arhalofenate and febuxostate drug interaction study is higher than doses of arhalofenate previously administered in our gout and T2DM programs, and may demonstrate an unacceptable safety and tolerability profile or lack of efficacy. We also plan to initiate one or more proof-of-concept studies for MBX-8025 in the first half of 2015. The success of arhalofenate and MBX-8025 will depend on several factors, including the following:

- successful enrollment and completion of clinical trials;
- recognition by the FDA and other regulatory authorities outside of the U.S. of orphan disease designation;
- receipt of marketing approvals from the FDA and regulatory authorities outside the U.S. for our product candidate;
- establishing commercial manufacturing capabilities by making arrangements with third-party manufacturers;
- launching commercial sales of the product, whether alone or in collaboration with others;
- acceptance of the product by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- a continued acceptable safety profile of the product following 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 arhalofenate, which would materially harm our business.

We have never obtained regulatory approval for a drug and we may be unable to obtain, or may be delayed in obtaining, regulatory approval for arhalofenate.*

We have never obtained regulatory approval for a drug. In the U.S. it is possible that the FDA may refuse to accept our New Drug Application (NDA) for substantive review or may conclude after review of our data that our application is insufficient to obtain regulatory approval of arhalofenate. If the FDA does not accept or approve our NDA, it may require that we conduct additional clinical, nonclinical or manufacturing validation studies and submit that data before it will reconsider our application. Depending on the extent of these or any other FDA required studies, approval of any NDA or application that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDA.

We currently do not know when we might commence our Phase 3 study of arhalofenate or achieve FDA approval of arhalofenate. We currently do not have the capital necessary to conduct or complete Phase 3 studies of arhalofenate and we may not be able to raise sufficient funds necessary to conduct this study. We believe that our existing cash will be sufficient to enable us to complete our Phase 2b study, which we anticipate completing in the second quarter of 2015. We currently believe that we will need to raise additional capital to continue our operations beyond the fourth quarter of 2015.

Any delay in obtaining, or an inability to obtain, regulatory approvals would prevent us from commercializing arhalofenate, generating revenues and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for arhalofenate, which would have a material adverse effect on our business and could potentially cause us to cease operations.

We depend on the successful completion of clinical trials for our product candidates, including 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 arhalofenate and MBX-8025, 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 three Phase 2 clinical studies of arhalofenate in gout. In addition, six clinical studies with MBX-8025 and five clinical studies with MBX-2982 have been completed. However, we have never conducted a Phase 3 clinical trial. The positive results we have seen to date in our Phase 2 clinical trials of arhalofenate for gout 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 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;
- 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 if we commence a Phase 3 clinical trial with arhalofenate and undertake additional clinical trials of our other product candidates MBX-8025 and MBX-2982. Before we commence a Phase 3 clinical trial for arhalofenate, we will need to raise substantial additional capital. We also will need to raise substantial additional capital in the future to complete the development and commercialization of MBX-8025 and 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 arhalofenate, or any other clinical trial we conduct, could cause the FDA to require that we repeat or conduct additional clinical studies. Despite the results reported in earlier clinical trials for 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 our product candidates, including arhalofenate. 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 never conducted a clinical trial of arhalofenate as a monotherapy for the treatment of gout flares without the use of colchicine. If arhalofenate does not demonstrate efficacy in the treatment of such flares in our Phase 2b clinical trial, our ability to successfully commercialize arhalofenate may be adversely affected.*

We have not previously conducted a clinical trial of arhalofenate for the purpose of measuring its effect on flare reduction and control without the use of colchicine. We are conducting a Phase 2b clinical trial to investigate the potential benefit of arhalofenate monotherapy with regard to flare prevention and serum uric acid (sUA) lowering. In addition, our Phase 2b study will investigate the benefits of two doses of arhalofenate monotherapy, including a higher dose than we studied in previous gout studies, without colchicine. If we do not obtain favorable efficacy and safety results in the Phase 2b trial, our ability to successfully develop and market arhalofenate could be adversely affected.

We have never formally investigated the potential of arhalofenate for a drug interaction with febuxostat. If arhalofenate has a significant drug interaction with febuxostat in our ongoing Phase 2 combination study, our ability to commercialize arhalofenate may be adversely affected.*

We have not previously conducted a drug interaction clinical trial of arhalofenate with febuxostat. Drug interaction studies are a common aspect of drug development required to determine the potential for two drugs when co-administered to affect each other's levels in the body. The existence of a significant drug interaction can alter the circumstance and way in which two drugs can be used together, up to and including the contraindication of their co-administration. We are conducting a Phase 2 clinical trial in gout patients with hyperuricemia to investigate the potential for a drug interaction between febuxostat and arhalofenate. In addition, this Phase 2 study will investigate the effects on serum uric acid reduction for each of two dose levels of arhalofenate with either of two dose levels of febuxostat. If we detect a significant drug interaction, or if the arhalofenate administered alone or when co-administered with febuxostat fails to significantly lower serum uric acid, our ability to successfully develop and market arhalofenate could be adversely affected.

We have never conducted a clinical trial of MBX-8025 for the indications which we are considering for MBX-8025. 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 not previously conducted a clinical trial of MBX-8025 for any of the indications for which we currently are considering. As a result, 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 FDA 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.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.

Clinical testing is expensive, difficult to design and implement, can take many years to complete, and is uncertain as to outcome. We may experience delays in clinical trials at any stage of development and testing of our product candidates. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of subjects, or be completed on schedule, if at all.

Events which may result in delays or unsuccessful completion of clinical trials, including our future clinical trials for arhalofenate, include the following:

- inability to raise funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA on final trial design;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;

- delays in reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical trial sites;
- delays in obtaining required institutional review board (IRB) approval at each site;
- delays in recruiting suitable patients to participate in a trial;
- delays in having subjects complete participation in a trial or return for post-treatment follow-up;
- delays caused by subjects dropping out of a trial due to side effects or otherwise;
- delays caused by clinical sites dropping out of a trial;
- time required to add new clinical sites; and
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials.

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

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

Arhalofenate has been studied in a total of 15 clinical trials with nearly a thousand 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.

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 modified risk evaluation and mitigation strategy;
- 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.

We have not obtained orphan drug designation for MBX-8025 for any indication and we may not be able to obtain or maintain orphan designation or obtain the benefits associated with orphan drug status, including market exclusivity.*

Regulatory authorities in some jurisdictions, including the United States and the European Union, or EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA or the European Medicines Agency, or EMA, from approving another marketing application for the same drug for that time period. The applicable period is seven years in the United States and ten years in the European Union. The EU exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of

patients with the rare disease or condition. In addition, the orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process. Also, regulatory approval for any product candidate may be withdrawn and other candidates may obtain approval before us. We have not obtained orphan designation for MBX-8025 for any indication, and may not be able to obtain designation or any of the potential benefits associated with it. Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the candidate from competition because different drugs can be approved for the same condition and the first entity with an orphan drug designation to receive regulatory approval for a particular indication will receive marketing exclusivity. Even after an orphan drug is approved, the FDA can subsequently approve another drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

If any product candidate that we successfully develop does not achieve broad market acceptance among physicians, patients, health care payors and the medical community, the revenues that it generates from its sales will be limited.

Even if arhalofenate, MBX-8025 or any other product candidates receive regulatory approval, the products may not gain market acceptance among physicians, patients, health care payors and the medical community. Coverage and reimbursement of our product candidates by third-party payors, including government payors, generally is also necessary for commercial success. The degree of market acceptance of any of our approved products will depend upon a number of factors, including:

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

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

Potential conflicts of interest arising from relationships and any related compensation with respect to clinical studies could adversely affect the process.

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

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

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

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

We cannot commercialize our product candidates, including arhalofenate and MBX-8025, until the appropriate regulatory authorities, such as the FDA, have reviewed and approved the product candidate. The regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval for our product candidates. Additional delays may result if a product candidate is brought before an FDA advisory committee, which could recommend restrictions on approval or recommend non-approval of the product candidate. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical studies and the review process. As a result, we cannot predict when, if at all, we will receive any future revenue from commercialization of any of our product candidates, including arhalofenate and MBX-8025. The FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons, including the following:

- we may be unable to demonstrate to the satisfaction of regulatory authorities that a product candidate is safe and effective for any indication;
- regulatory authorities may not find the data from nonclinical studies and clinical studies sufficient or may differ in the interpretation of the data;
- regulatory authorities may require additional nonclinical or clinical studies;
- the FDA or foreign regulatory authority might not approve our third party manufacturers' processes or facilities for clinical or commercial product;
- the FDA or foreign regulatory authority may change its approval policies or adopt new regulations;
- the FDA or foreign regulatory authorities may disagree with the design or implementation of our clinical studies;
- the FDA or foreign regulatory authority may not accept clinical data from studies that are conducted in countries where the standard of care is potentially different from that in the U.S.;
- the results of clinical studies may not meet the level of statistical significance required by the FDA or foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks; and
- the data collection from clinical studies of our product candidates may not be sufficient to support the submission of a NDA or other submission or to obtain regulatory approval in the U.S. or elsewhere.

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

Even if we obtain regulatory approval for arhalofenate, MBX-8025 and our other product candidates, we will still face extensive regulatory requirements and our products may face future development and regulatory difficulties.

Even if we obtain regulatory approval in the U.S., the FDA may still impose significant restrictions on the indicated uses or marketing of our product candidates, including arhalofenate and MBX-8025, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. For example, the labeling ultimately approved for our product candidates, including arhalofenate and MBX-8025, may include restrictions on use due to the specific patient population and manner of use in which the drug was evaluated and the safety and efficacy data obtained in those evaluations.

Arhalofenate, MBX-8025 and our other product candidates will also be subject to additional ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping and reporting of safety and other post-market information. The holder of an approved NDA is obligated to monitor and report AEs and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. Furthermore, promotional materials must be approved by the FDA prior to use for any drug receiving accelerated approval, the pathway we are pursuing for arhalofenate in the U.S.

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

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

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

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

Even if we obtain FDA approval for arhalofenate, MBX-8025 or any of our other products in the U.S., we may never obtain approval for or commercialize arhalofenate, MBX-8025 or any of our other products outside of the U.S., which would limit our ability to realize their full market potential. *

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

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

Health care providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other health care laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state health care laws and regulations, include the following:

- the federal health care anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal health care programs such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any health care benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services;
- the federal transparency requirements under the PPACA require manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving health care items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

Efforts to ensure that our business arrangements with third parties will comply with applicable health care laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other health care laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded health care programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded health care programs.

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

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

In the U.S., the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Medicare Modernization Act) changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

More recently, in March 2010, the Health Care Reform Law was enacted to broaden access to health insurance, reduce or constrain the growth of health care spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The Health Care Reform Law revises the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the new law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. New provisions affecting compliance have also been enacted, which may affect our business practices with health care practitioners. We will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be.

Risks Related to Our Reliance on Third Parties

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

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

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

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

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

It is our expectation that only one supplier of drug substance and one supplier of drug product will be qualified by the FDA. If supply from an approved vendor is interrupted, there could be a significant disruption in commercial supply of arhalofenate. An alternative vendor would need to be qualified through an NDA supplement which would be expensive and could result in further delay. The FDA or other regulatory agencies outside of the U.S. may also require additional studies if a new drug substance or drug product supplier is relied upon for commercial production. These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of arhalofenate, and cause us to incur additional costs. Furthermore, if our suppliers fail to deliver the required commercial quantities of active pharmaceutical ingredient on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our supply chain for arhalofenate may be delayed, which could inhibit our ability to generate revenues.

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

We are modifying the drug substance production process for arhalofenate at the selected commercial manufacturer to cost effectively remove impurities. As the modified process is scaled up it may reveal manufacturing challenges or previously unknown impurities which could require resolution in order to proceed with our planned clinical trials and obtain regulatory approval for the commercial marketing of arhalofenate. In the future, we may identify manufacturing issues or impurities which could result in delays in the clinical program and regulatory approval for arhalofenate, increases in our operating expenses, or failure to obtain or maintain approval for arhalofenate.

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

- the inability to meet our product specifications and quality requirements consistently;
- a delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- a failure to comply with cGMP and similar foreign standards;

- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- the reliance on a limited number of sources, and in some cases, single sources for key materials, such that if we are unable to secure a sufficient supply of these key materials, we will be unable to manufacture and sell our product candidates in a timely fashion, in sufficient quantities or under acceptable terms;
- the lack of qualified backup suppliers for those materials that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier;
- carrier disruptions or increased costs that are beyond our control; and
- the failure to deliver our products under specified storage conditions and in a timely manner.

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

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

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

We and our CSPs are required to comply with the FDA's guidance, which follows the International Conference on Harmonization Good Clinical Practice (ICH GCP), which are regulations and guidelines enforced by the FDA for all of our product candidates in clinical development. The FDA enforces the ICH GCP through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CSPs fail to comply with the ICH GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. For example, upon inspection, the FDA may determine that our Phase 3 clinical trial for arhalofenate, does not comply with the ICH GCP. In addition, our Phase 3 clinical trials for arhalofenate will require a sufficiently large number of test subjects to evaluate the safety and effectiveness of arhalofenate. Accordingly, if our CSPs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat these Phase 3 clinical trials, which would delay the regulatory approval process.

Our CSPs are not our employees, and we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and nonclinical programs. These CSPs may also have relationships with other entities, including our competitors, for whom they may also be conducting clinical studies, or other drug development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CSPs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CSPs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize arhalofenate or our other product candidates. As a result, our financial results and the commercial prospects for arhalofenate and any other product candidates that we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

Risks Related to Commercialization of Our Product Candidates

The commercial success of arhalofenate, MBX-8025 and our other product candidates will depend upon the acceptance of these products by the medical community, including physicians, patients and health care payors.

If any of our product candidates, including arhalofenate and MBX-8025, receive marketing approval, they may nonetheless not gain sufficient market acceptance by physicians, patients, health care payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any of our product candidates, including arhalofenate and MBX-8025, will depend on a number of factors, including the following:

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

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

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

We currently do not have an organization for the sales, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved, including arhalofenate and MBX-8025, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. We may enter into strategic partnerships with third parties to commercialize our product candidates, including arhalofenate and MBX-8025.

If we are unable to build our own sales force or negotiate a strategic partnership for the commercialization of arhalofenate, we may be forced to delay the potential commercialization of arhalofenate, or reduce the scope of our sales or marketing activities for arhalofenate. If we elect to increase our expenditures to fund commercialization activities ourselves, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring arhalofenate to market or generate product revenue.

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

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

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

If our product candidates are approved for commercialization, we intend to enter into agreements with third parties to market those product candidates outside the U.S., including for arhalofenate and MBX-8025. We expect that we will be subject to additional risks related to international operations, including the following:

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, pandemics, or natural disasters including earthquakes, typhoons, volcanic eruptions, floods and fires.

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

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

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

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

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

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

Formulary approval and reimbursement may not be available for arhalofenate, MBX-8025 and our other product candidates, which could make it difficult for us to sell our products profitably.

Obtaining formulary approval can be an expensive and time consuming process. We cannot be certain if and when we will obtain formulary approval to allow us to promote our product candidates, including arhalofenate and MBX-8025, into our target markets. Failure to obtain timely formulary approval will limit our commercial success.

Furthermore, market acceptance and sales of arhalofenate, MBX-8025 or any other product candidates that we develop, will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A prevailing trend in the U.S. health care industry and elsewhere is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. We cannot be sure that reimbursement will be available for arhalofenate, or any other product candidates. Also, reimbursement amounts may reduce the demand for, or the price of, our products. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize arhalofenate, or any other product candidates that we develop.

There have been a number of legislative and regulatory proposals to change the health care system in the U.S. and in some foreign jurisdictions that could affect our ability to sell any future products profitably. These legislative and regulatory changes may negatively impact the reimbursement for any future products, following approval. The availability of generic treatments may also substantially reduce the likelihood of reimbursement for any future products, including arhalofenate. The application of user fees to generic drug products will likely expedite the approval of additional generic drug treatments. We expect to experience pricing pressures in connection with the sale of arhalofenate and any other product candidate that we develop, due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes.

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

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

Even if we receive regulatory approval for arhalofenate or MBX-8025, we will be subject to ongoing FDA and other regulatory obligations and continued regulatory review, which may result in significant additional expense and limit our ability to commercialize arhalofenate or MBX-8025.

Any regulatory approvals that we or potential collaboration partners receive for arhalofenate, MBX-8025 or future product candidates, may also be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing studies. In addition, even if approved, the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for any product will be subject to extensive and ongoing regulatory requirements. The subsequent discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, may result in restrictions on the marketing of the product, and could include withdrawal of the product from the market.

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

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

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

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

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

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

The success of our business depends primarily upon our ability to identify, develop and commercialize product candidates. Because we have limited financial and managerial resources, we focus on product candidates for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater commercial potential. We may focus our efforts and resources on product candidates that ultimately prove to be unsuccessful.

If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights.

Risks Related to Our Intellectual Property

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

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

patent applications, an interference proceeding in the U.S. can be provoked by a third party or instituted by us to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license it from the prevailing party, which may not be available on commercially reasonable terms or at all.

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

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

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

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

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

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our

product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our products or product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

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

We are a party to a number of technology licenses that are important to our business and expect to enter into additional licenses in the future. For example, we rely on an exclusive license to certain patents, proprietary technology and know-how from DiaTex, which include arhalofenate. During the term of the exclusive license with DiaTex we may perform research and development of compounds and products for the treatment of human disease based on the patents, proprietary technology and know-how from DiaTex. If we fail to comply with our obligations under our agreement with DiaTex, including our obligations to pay royalty payments during the development and commercialization of arhalofenate, or our other license agreements, or if we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license, including in the case of the DiaTex license, arhalofenate, which would have a materially adverse effect on our business.

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

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

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

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

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

Risks Related to Our Business Operations and Industry

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

We are highly dependent on principal members of our executive team listed under "Business—Executive Officers of Registrant" of our Annual Report on Form 10-K as filed with the SEC on March 31, 2014. While we have entered into employment agreements or offer letters with each of our executive officers, any of them could leave our employment at any time, as all of our employees are "at will" employees. We do not maintain "key person" insurance for any of our executives or other employees. Recruiting and retaining other qualified employees for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. We also experience competition from universities and research institutions for the hiring of scientific and clinical personnel. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. In addition, failure of any of our clinical studies may make it more challenging to recruit and retain qualified personnel. If we are unable to successfully recruit key employees or replace the loss of services of any executive or key employee, it may adversely affect the progress of our research, development and commercialization objectives.

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

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

As of September 30, 2014, we had 16 full-time employees. As our company matures, we expect to expand our employee base to increase our managerial, clinical, scientific and engineering, operational, sales, and marketing teams. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize arhalofenate and our other product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Risks Relating to Owning Our Common Stock

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

Our common stock is listed on the NASDAQ Capital Market under the symbol "CBAY". Trading volume for our common stock has been very limited. The historical trading prices of our common stock on the NASDAQ Capital Market may not be indicative of the price levels at which our common stock will trade in the future, and we cannot predict the extent to which investor interest in us generally will lead to the development of an active public trading market for our common stock or how liquid that public market may become.

Our stock price may be volatile, and our stockholders' investment in our stock could decline in value.

The trading price of our common stock, if one develops, is likely to be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including:

- adverse results or delays in preclinical testing or clinical trials;
- inability to obtain additional funding;
- any delay in filing an IND or NDA for any of our future product candidates an any adverse development or perceived adverse development with respect to the FDA's review of that IND or NDA;
- failure to maintain our existing collaborations or enter into new collaborations;

- failure of our collaboration partners to elect to develop or commercialize product candidates under our collaboration agreements or the termination of any programs under our collaboration agreements;
- failure by us or our licensors and collaboration partners to prosecute, maintain or enforce our intellectual property rights;
- failure to successfully develop and commercialize our future product candidates;
- changes in laws or regulations applicable to future products;
- inability to obtain adequate product supply for our future product candidates or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we may provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us, our collaboration partners or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future; and
- trading volume of our common stock.

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

Our executive officers, directors and principal stockholders own a significant percentage of our stock and will be able to exert significant control over matters submitted to our stockholders for approval. *

As reported under "Security Ownership of Certain Beneficial Owners and Management" in our prospectus filed with the SEC on July 22, 2014, our executive officers, directors and stockholders who own more than 5% of our outstanding common stock, together beneficially own a significant percentage of our common stock. Therefore, these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to influence all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to influence elections of directors, amendments to our organizational documents, or approval of any merger, sale of assets, or other major corporate action. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

We have identified material weaknesses in our internal controls over financial reporting. *

Maintaining effective internal controls over financial reporting is necessary for us to produce accurate financial statements on a timely basis. As noted in "Part I, Item 4. Controls and Procedures," we have identified material weaknesses in our internal control over financial reporting. We are currently in the process of remediating these material weaknesses by, among other things, designing and implementing new procedures and controls as described in "Part I, Item 4 Controls and Procedures." We expect to continue to incur costs associated with implementing appropriate processes and internal controls, which could include new employee compensation costs and fees for additional audit and consulting services, which could negatively affect our financial condition and operating results.

However, effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud. Our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act until the later of the year following our first annual report required to be filed with the SEC or the date we are no longer an "emerging growth company" as defined in the JOBS Act, because we are taking advantage of the exemptions contained in the JOBS Act. To build the infrastructure to allow us to assess the effectiveness of our internal control over financial reporting, we hired our Controller in the first quarter of 2014 to assist us in improving our accounting systems, disclosure policies, procedures and controls. This effort is on-going and will be costly and time

consuming. If we are unsuccessful in building an appropriate accounting infrastructure, we may not be able to prepare and disclose, in a timely manner, our financial statements and other required disclosures, or comply with existing or new reporting requirements. We cannot assure you that there will not be material weaknesses in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to achieve effective internal control over financial reporting, or if our independent registered public accounting firm determines we continue to have a material weakness in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by The NASDAQ Stock Market, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

We have recently become a public company and we will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial new time to compliance initiatives.

We became a public company in October 2013, and as a result, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the Securities and Exchange Commission, or the SEC, and any stock market upon which we may list, have imposed various requirements on public companies. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Recent legislation permits smaller "emerging growth companies" to implement many of these requirements over a longer period and up to five years from the pricing of their public offerings. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.

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

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

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

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders. For example, in July 2014 we completed a public offering of our common stock which resulted in the issuance of 4,600,000 shares of our common stock.

Pursuant to our equity incentive plans, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares available for future grant under our equity incentive plans as of September 30, 2014 was 310,168 shares.

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

We do not anticipate paying cash dividends in the future. As a result, only appreciation of the price of our common stock, which may never occur, will provide a return to stockholders. Investors seeking cash dividends should not invest in our common stock. In addition, our ability to pay cash dividends is currently prohibited without the prior consent of the lender pursuant to the terms of our loan and security agreement with Silicon Valley Bank and Oxford.

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

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

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

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

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Unregistered Sale of Equity Securities

From July 1, 2014, to September 30, 2014, we issued an aggregate of 19,962 shares of common stock to one of our stockholders upon the exercise of warrants exercisable for shares or our common stock. The 19,962 shares of common stock were issued pursuant to a cashless exercise provision as provided in the warrants in exchange for an aggregate of 40,908 shares of our common stock. The issuances were in reliance on Rule 506 and Regulation D under the Securities Act.

Use of Proceeds

We consummated a public offering or our common stock on a registration statement on Form S-1 (File No. 333-195127) that was declared effective by the SEC on July 21, 2014, pursuant to which we sold 4,600,000 shares of our common stock, including shares sold in connection with the exercise by the underwriters in the offering of an over-allotment of 600,000 shares, at a price of $5.50 per share, for aggregate gross proceeds of $25.3 million which we refer to as our 2014 public offering. The offering was made pursuant to a prospectus dated July 21, 2014. Cowen and Company, LLC and Stifel, Nicolaus & Company, Incorporated were the managing underwriters in the offering.

We paid to the underwriters underwriting discounts and commissions of $1.5 million, and incurred offering expenses of approximately $0.8 million in connection with the offering (including a financial advisory fee to National Securities Corporation, one of the underwriters in this offering, of $75,900, a financial advisory fee to Trout Capital LLC of $151,800, and reimbursement of reasonable out-of-pocket expenses incurred by to Trout Capital LLC of approximately $10,000 in connection with serving as our financial advisor in connection with the offering). The net offering proceeds to us, after deducting underwriting discounts, commissions and offering expenses, were approximately $23.0 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

Upon receipt, the net proceeds from our 2014 public offering were invested in cash and cash equivalents. As of September 30, 2014, we estimate that we had used approximately $1.8 million of the proceeds on the development of MBX-8025 and ongoing development of arhalofenate and approximately $0.8 million for working capital, capital expenditures and other general corporate purposes. The remaining $20.4 million is held in cash, cash equivalents and short term investments. There has been no material change in the expected use of the net proceeds from our public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) on July 22, 2014 (File No. 333-195127).

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 14, 2014

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

Date: November 14, 2014

INDEX TO EXHIBITS

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation (Filed with the SEC as Exhibit 3.1 to our Amendment No. 2 to Registration Statement on Form 10, filed with the SEC on October 17, 2013, SEC File No. 000-55021).
3.2	Amended and Restated By-Laws. (Filed with the SEC as Exhibit 3.2 to our Amendment No. 2 to Registration Statement on Form 10, filed with the SEC on October 17, 2013, SEC File No. 000-55021).
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Form of Registration Rights Agreement (Filed with the SEC as Exhibit 4.2 to our Amendment No. 2 to Registration Statement on Form 10, filed with the SEC on October 17, 2013, SEC File No. 000-55021).
4.3	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).
10.1	PPARδ License Agreement, dated June 20, 2006, by and between Metabolex, Inc. and Janssen Pharmaceutica NV *
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

* Confidential treatment has been requested for portions of this exhibit.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit 10.1

PPAR-δ LICENSE AGREEMENT

THIS LICENSE AGREEMENT (the "**Agreement**") is made and entered into as of the Effective Date (as defined below), by and between **METABOLEX, INC.**, a Delaware corporation having its principal place of business at 3876 Bay Center Place, Hayward, CA 94545 ("**Metabolex**"), and **JANSSEN PHARMACEUTICA NV**, a corporation organized under the laws of Belgium having a place of business at 30 Turnhoutseweg, 2340 Beerse, Belgium ("**Janssen**"). Metabolex and Janssen are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Ortho-McNeil, Inc. (an Affiliate of Janssen) and Metabolex are party to a Strategic Alliance Agreement setting forth the scope and terms of a strategic alliance between the Parties in the area of metabolic diseases;

WHEREAS, as part of such alliance, Metabolex desires to obtain from Janssen an exclusive, worldwide license under certain patents, know-how and other intellectual property relating to Janssen's PPAR-δ program; and

WHEREAS, Janssen is willing to grant such license under the terms and conditions set forth in this Agreement.

NOW, THEREFORE, the Parties agree as follows:

ARTICLE 1

DEFINITIONS

As used herein, the following terms shall have the following meanings:

1.1 "Affiliate" means, with respect to a particular Party, a corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party. For the purposes of the definition in this Section 1.1, the word "**control**" (including, with correlative meaning, the terms "controlled by" or "under common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of at least fifty percent (50%) of the voting stock of such entity, or by contract or otherwise.

1.2 "Confidential Information" has the meaning set forth in Section 6.1.

1.3 "Controlled" means, with respect to an item of Information or an intellectual property right, that a Party or one of its Affiliates owns or has a license to such item or right and has the ability to disclose to the other Party and/or grant a license or sublicense under such item or right as provided for in this Agreement without violating the terms of any agreement with any Third Party, or other obligation to any Third Party.

1.4 "CTA" means a clinical trial authorization, as described in Article 9 of Directive 2001/20/EC of the European Parliament and of the Council.

1.5 "Diligent Efforts" means, with respect to a Party's obligation under this Agreement, the level of efforts required to carry out a task or obligation in a manner consistent with its normal business practices the Party would devote to a product at a similar stage of development or commercialization and of similar market potential, profit potential or strategic value, based on conditions then prevailing.

1.6 "Effective Date" means the Effective Date as defined in the PPAR-γ License Agreement.

1.7 "Execution Date" means June 20, 2006, the date upon which this Agreement has been executed and delivered by both Parties.

1.8 "FDA" means the U.S. Food and Drug Administration, or a successor federal agency thereto.

1.9 "First Commercial Sale" means, with respect to a PPAR-δ Product in a particular country, the first commercial sale of such product in such country after all needed Regulatory Approvals have been obtained in such country.

1.10 "IND" means an investigational new drug application filed with the FDA for approval to commence human clinical trials, or any equivalent application filed with any equivalent regulatory authority in a country other than the U.S.

1.11 "Information" means all tangible and intangible (a) information, techniques, technology, practices, trade secrets, inventions (whether patentable or not), methods, knowledge, know-how, skill, experience, data, results (including pharmacological, toxicological and clinical test data and results), analytical and quality control data, results or descriptions, software and algorithms and (b) compositions of matter, cells, cell lines, assays, animal models and physical, biological or chemical material.

1.12 "Major Market" means France, Germany, Italy, Japan, Spain, the United Kingdom, or the U.S.

1.13 "Metabolex Know-How" means all Information that (a) is Controlled by Metabolex or its Affiliates during the Term, (b) is developed or acquired by Metabolex or its

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Affiliates after the Effective Date and (c) relates to a PPAR-δ Compound or a PPAR-δ Product or its development, manufacture, promotion or use, but excluding the Metabolex Patents, PPAR-δ Patents, and PPAR-δ Know-How.

1.14 "Metabolex Patents" means all Patents (other than PPAR-δ Patents) that (a) are filed during the Term with a priority date after the Effective Date; (b) are Controlled during the Term by Metabolex or a Metabolex Affiliate; and (c) claim or cover the composition of matter, manufacture or use of a PPAR-δ Compound or a PPAR-δ Product.

1.15 "NDA" means a New Drug Application filed pursuant to the requirements of the FDA, as more fully defined in 21 C.F.R. § 314.5 et seq. or any equivalent application filed with any equivalent regulatory authority in a country other than the U.S.

1.16 "Net Sales" means, with respect to a given period of time, **[*]**, less the following deductions and offsets that are actually incurred, allowed, accrued and/or taken and are specifically allocated with respect to such sale or distribution, but solely to the extent that such deductions or offsets are not otherwise recovered by or reimbursed to Metabolex or its Affiliates, distributors or sublicensees:

[*]

The methodology for calculating (a) – (f), on a country-by-country basis, shall conform to generally accepted accounting principles consistently applied by Metabolex and its Affiliates across its product lines.

Net Sales shall also include the fair market value of all consideration received by Metabolex and its Affiliates and their distributors and sublicensees in respect of any sale of PPAR-δ Products, whether such consideration is in cash, payment in kind, exchange for value or another form.

In the case of discounts, reductions, payments or rebates offered for the PPAR-δ Products where the PPAR-δ Products are sold to a customer as a grouped set of products and/or services, Metabolex may discount the bona fide list price of a PPAR-δ Product by no more than the average weighted percentage discount (off of the applicable list prices) of all the products of Metabolex and/or its Affiliates in such particular grouped set of products. The methodology for calculating the "average weighted percentage discounts" for PPAR-δ Products will be consistent with Metabolex's and its Affiliates' usual course of dealing with all its products other than the PPAR-δ Products. An example of the calculation of "average weighted percentage discount" for a particular grouped set is set forth in the attached **Exhibit A**.

If a PPAR-δ Product is sold in the form of a combination product containing both a PPAR-δ Product and one or more independently therapeutically active pharmaceutical molecules that are not PPAR-δ Products (for the purpose of this Section 1.16, a "**Combination Product**"), [*].

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

[*]

If Metabolex (or its Affiliate) sublicenses the development and/or commercialization of a PPAR-δ Product to a Third Party in consideration of the payment (inter alia) of royalties by such sublicensee on sales by such sublicensee of the PPAR-δ Product, then Metabolex (or its Affiliate) shall use commercially reasonable efforts to use a definition of net sales in the sublicense agreement between Metabolex and such sublicensee that exactly matches the definition of "Net Sales" as used in this Agreement. However, in the event such definitions differ, for purposes of calculating the royalty owed by Metabolex to Janssen based on such sublicensee's sales of such PPAR-δ Product, the definition of "Net Sales" as used in this Agreement, solely for purposes of calculating such royalty owed, shall be deemed to be the definition of net sales in the sublicense agreement between Metabolex (or such Affiliate) and such sublicensee, *provided, however*, that (i) the two definitions are substantially similar and (ii) the methodology for calculating any deductions or offsets listed in such definition, on a country-by-country basis, conforms to generally accepted accounting principles consistently applied by such sublicensee across its product lines.

1.17 "Other Product" means any pharmaceutical product (other than a PPAR-δ Product) containing a Selective PPAR-δ Modulator, and including all formulations, line extensions and modes of administration thereof.

1.18 "Patents" means (a) U.S. patents, re-examinations, reissues, renewals, extensions and term restorations, and foreign counterparts thereof, and (b) pending applications for U.S. patents, including, without limitation, provisional applications, continuations, continuations-in-part, divisional and substitute applications, inventors' certificates, and extensions, and foreign counterparts of any of the foregoing.

1.19 "Phase III Trial" means that portion of the clinical development program that provides for trials of a PPAR-δ Product in an extended human patient population designed to obtain data determining efficacy and safety of the PPAR-δ Product to support Regulatory Approvals in the proposed therapeutic indication as more fully defined in 21 C.F.R. § 312.21(c), or its successor regulation, or the equivalent in any foreign country.

1.20 "PPAR-δ Compound" means: (a) any of the compounds known as [*] (each as described in **Exhibit B**); (b) any other compound that is a Selective PPAR-δ Modulator [*] as defined in: [*], or [*] or [*], and/or [*]; and (c) any [*] of any of the foregoing compounds.

1.21 "PPAR-δ Know-How" means all Information that is Controlled by Janssen or its Affiliates as of the Effective Date and relates to a PPAR-δ Compound, or is otherwise necessary for the development, manufacture, promotion, or use of a PPAR-δ Compound, but excluding the PPAR-δ Patents. For clarity, PPAR-δ Know-How shall include the Product Data Package.

1.22 "PPAR-δ Patents" means all Patents that are Controlled during the Term by Janssen or a Janssen Affiliate and that include one or more claims that claim or cover a PPAR-δ Compound, or the manufacture or use of a PPAR-δ Compound, including without limitation

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those listed on **Exhibit C**. In addition, "PPAR-δ Patents" shall include all Patents that are Controlled as of the Effective Date by Janssen or a Janssen Affiliate to the extent that such Patents include one or more claims that claim or cover the formulation, manufacture or use of a PPAR-δ Product as it exists as of the Effective Date.

1.23 "PPAR-δ Product" means any pharmaceutical product that contains a PPAR-δ Compound, and including all formulations, line extensions and modes of administration thereof.

1.24 "PPAR-γ License Agreement" means the Development and License Agreement executed on June __, 2006, by and between Metabolex and Ortho-McNeil, Inc.

1.25 "Product Data Package" shall mean any and all files, data, records and other Information (including without limitation regulatory documents, pre-clinical and clinical protocols, data, and reports, product complaint files, and adverse event files) relating to development of PPAR-δ Compounds or PPAR-δ Products anywhere in the world, to the extent such files, data, records or Information are Controlled by Janssen or its Affiliates.

1.26 "Regulatory Approval" means any and all approvals (including supplements, amendments, pre- and post-approvals, pricing and reimbursement approvals), licenses, registrations or authorizations of any national, supra-national (e.g., the European Commission or the Council of the European Union), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, that are necessary for the manufacture, distribution, use or sale of a PPAR-δ Product in the particular regulatory jurisdiction.

1.27 "Selective PPAR-δ Modulator" means any small molecule compound that (a) [*] interacts with the PPAR-δ receptor to [*] or [*], and (b) shows activity toward [*] the PPAR-δ receptor in the [*] assay using [*] (or any [*] thereof). To constitute a Selective PPAR-δ Modulator, the compound must not [*] (i) [*] or (ii) [*]. For the purposes of clause (i) of this Section 1.27, "[*]" means [*] in either the [*] and/or [*], as applicable, that is [*] obtained in the [*] assay. For the purposes of clause (ii) of this Section 1.27, "[*]" means [*] of the [*] of the compound for the [*] (measured at [*] determined in the [*] assay) in the generally accepted assay for the [*] (or if there is no such generally accepted assay, a validated assay for the [*]). Notwithstanding the above, the term "Selective PPAR-δ Modulator" shall include, without limitation, [*].

1.28 "Term" means the term of this Agreement as provided in Section 9.1.

1.29 "Third Party" means any Person other than (a) Metabolex, (b) Janssen, or (c) an Affiliate of either Metabolex or Janssen.

1.30 "U.S." means the United States of America, including its territories, protectorates and possessions.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

1.31 "Valid Claim" means (i) a valid and enforceable claim of an issued, unexpired PPAR-δ Patent, or (ii) a claim in any pending application for a PPAR-δ Patent for which not more than [*] years have elapsed from the [*]. A claim of an issued, unexpired patent shall be deemed to be valid and enforceable unless and until it has been held to be invalid and/or unenforceable by a final judgment of a court of competent jurisdiction from which no further appeal can be taken. If a claim of a patent application that ceased to be a Valid Claim under clause (ii) of this Section 1.31 later issues or grants as a patent within the scope of clause (i) of this Section 1.31, then such claim shall again be considered to be a Valid Claim, effective as of the earlier of the grant or issuance of such patent.

ARTICLE 2

LICENSES

2.1 License Grant. Subject to the terms and conditions of this Agreement, Janssen hereby grants to Metabolex an exclusive (even as to Janssen and its Affiliates), worldwide, royalty-bearing license, with the right to grant sublicenses to Affiliates and/or Third Parties through multiple tiers, under the PPAR-δ Patents and PPAR-δ Know-How solely to research, develop, use, market, offer for sale, sell, import, manufacture, have manufactured, and distribute the PPAR-δ Products.

2.2 Third Party Licenses. Janssen shall be solely responsible for all costs and expenses of any licenses in effect as of the Effective Date between a Third Party and Janssen or its Affiliates related to the PPAR-δ Products. Subject to Section 4.2(a), Metabolex shall be solely responsible for all costs and expenses of any other license required in order to lawfully develop and commercialize the PPAR-δ Products.

2.3 No Other Licenses. Neither Party grants to the other Party any rights or licenses in or to any intellectual property, whether by implication, estoppel, or otherwise, other than the license rights that are expressly granted under this Agreement.

2.4 No Non-Permitted Use. Metabolex hereby covenants that it shall not, nor shall it cause or permit any Affiliate or sublicensee to use or practice, any PPAR-δ Patents or PPAR-δ Know-How, for any purposes other than those expressly permitted in Section 2.1, or Section 9.5(f) or (h). Janssen hereby covenants that it shall not, nor shall it cause or permit any Affiliate or sublicensee to use or practice any PPAR-δ Patents or PPAR-δ Know-How, for any purposes other than those expressly set forth in Section 9.5(a).

2.5 Third Party Contracts. Metabolex shall use reasonable commercial efforts to ensure that each Third Party contract that Metabolex (or any Affiliate) enters into solely related to PPAR-δ Products contains provision(s) permitting such Third Party contract to be assigned in accordance with Section 9.5(e). As to other contracts entered into by Metabolex (or its Affiliates) that relate to PPAR-δ Products, Metabolex shall reasonably cooperate (if requested by Janssen after termination of the Agreement under Article 9) to assist Janssen in obtaining the benefits of such contracts. To the extent any such Third-Party contract relates to products or services generally available upon commercially reasonable terms, Metabolex shall not be required to assign such agreement(s), or provide such assistance (as applicable), to Janssen.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

2.6 Sublicensee Agreements. Metabolex shall, in each sublicense that it grants hereunder, require the sublicensee to transfer any regulatory filings with respect to any PPAR-δ Product or PPAR-δ Compound in the event of a termination of this Agreement or such sublicense, to Janssen if this Agreement terminates, and to Metabolex if only such sublicense terminates.

2.7 Exclusivity.

(a) Metabolex. Metabolex hereby covenants that Metabolex and its Affiliates shall not [*] for the period of [*], or until [*], any compound (other than a PPAR-δ Compound), or product that contains a compound (other than a PPAR-δ Product), that has [*] that such compound or product [*] unless that compound, or compound in the product, also has [*] that is either (i) [*] or (ii) [*], as well as [*] that is not [*] (such compound or product that [*] hereinafter referred to as an **"Excluded Product**"). If the product is a combination product (i.e., it contains multiple independently therapeutically active pharmaceutical molecules), the product shall be analyzed on a therapeutically active pharmaceutical molecule by therapeutically active pharmaceutical molecule basis to determine if it is an Excluded Product. Notwithstanding the above, [*] shall be deemed to be Excluded Products.

(b) Metabolex Sublicensees. Metabolex hereby covenants that any sublicense related to the [*] of a PPAR-δ Product that Metabolex or its Affiliates grant under this Agreement shall include a covenant by the sublicensee that such sublicensee shall not [*] for the period of [*], or until [*]. Metabolex hereby agrees to use reasonable efforts to enforce such covenant [*] if it, or its Affiliates, become aware of a breach or anticipated breach of such covenant by any sublicensee.

(c) Janssen. Janssen hereby covenants that Janssen and its Affiliates shall not [*] for the period of [*], or until [*].

(d) [*]. For the purposes of this Section 2.7, [*] means [*] that is responsible for the achievement of a [*] in one of the [*] used to [*] in the [*], which [*] as indicated in the [*] and [*] may be used to [*].

(e) Exception for Acquired Excluded Products. Notwithstanding the foregoing, if either Party or any of its respective Affiliates, enters into a definitive agreement with respect to a merger or acquisition by operation of which such Party or its Affiliate would (i) acquire an Excluded Product that at the time of the closing of the acquisition [*] or (ii) be acquired by, or merge with, a Third Party that has an Excluded Product that at the time of the closing of the acquisition [*], then such Party or its Affiliate (or the entity that acquired such Party or its Affiliate or the entity into which such Party or its Affiliate has merged) shall have [*] from the execution date of such definitive agreement to divest itself of such Excluded Product and, during such [*] period, the [*] of such Excluded Product shall be deemed to be not in

violation of Section 2.7(a) or Section 2.7(c), as applicable. Such divestiture can occur by either (1) an outright sale to a Third Party of all rights to such Excluded Product, or (2) an out-license (exclusive as to the divesting Party and its Affiliates) to a Third Party of all rights to [*] such Excluded Product; *provided, however*, that the divesting Party or its Affiliate must not exercise or have the ability to exercise any role, or influence in any manner, the [*] of such Excluded Product. If a Party or its Affiliate fails to divest itself of such Excluded Product during such [*] period, then if such Party is (A) Metabolex, then [*]; or (B) Janssen, then Metabolex shall have the right [*], at its discretion, upon written notice to Janssen, to [*] and/or [*] under this Agreement.

ARTICLE 3

DEVELOPMENT & COMMERCIALIZATION

3.1 Development and Commercialization of PPAR-δ Compounds. Subject to Section 3.6, Metabolex shall have full control and responsibility over the research, development and registration (including but not limited to, clinical activities and submissions to regulatory agencies, and all expenses related thereto) of any PPAR-δ Products, subject to the terms of this Agreement. Metabolex shall use Diligent Efforts to conduct all such research, development, and regulatory activities.

3.2 Development Information and Reporting. Metabolex shall use Diligent Efforts to prepare and maintain complete and accurate records regarding the worldwide clinical development of PPAR-δ Products. Metabolex shall provide to Janssen on a semi-annual basis a summary of the development efforts being conducted on PPAR-δ Product and the results of such development. Metabolex shall also provide to Janssen copies of all FDA and other Regulatory Authority communications associated with Major Market filings and shall inform Janssen promptly following the occurrence of any significant development event that occurs relating to such PPAR-δ Products (e.g. initiation or completion of a clinical trial, submission of a U.S. or international regulatory filing, receipt of a response to such U.S. or international regulatory filing, or serious adverse clinical safety event associated with a PPAR-δ Product).

3.3 Diligence in Development of PPAR-δ Products. Metabolex shall use Diligent Efforts to clinically develop at least one PPAR-δ Product under this Agreement, provided that in Metabolex's reasonable judgment it is commercially feasible to file for Regulatory Approval for such PPAR-δ Product in at least the U.S. and the other Major Markets.

3.4 Technology Transfer. Janssen and its Affiliates shall cooperate with Metabolex and provide access and transfer to Metabolex of its PPAR-δ Know-How by such dates after the Effective Date as are reasonably requested by Metabolex. For the avoidance of doubt, neither providing access to nor transfer of any PPAR-δ Know-How pursuant to this Section 3.4 shall alter the ownership or other rights of any Party or its Affiliates with respect to such PPAR-δ Know-How. Each Party shall be responsible for its own costs and expenses related to any such cooperation, *provided however*, that the costs of the transfer of any Materials by Janssen and its Affiliates shall be borne by Janssen.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

3.5 Materials Transfer. In order to facilitate the technology transfer provided in Section 3.4 and facilitate Metabolex's research and development of PPAR-δ Products, Janssen shall provide to Metabolex upon the prior written request of Metabolex, at no charge, the biological material, chemical compounds and Information Controlled by Janssen and its Affiliates listed on **Exhibit D** that Janssen and/or its Affiliates have on hand at the relevant time, and other material reasonably requested by Metabolex prior to [*] that Janssen and/or its Affiliates have on hand at the relevant time (collectively, the "**Materials**") for use by Metabolex solely to research and develop PPAR-δ Products. To the extent that such Materials consist of reports that are in the process of being written/completed as of the relevant time, Janssen agrees to write/complete such reports prior to providing them to Metabolex. It is agreed that Janssen and/or its Affiliates shall transfer to Metabolex upon prior written request of Metabolex, all of its stock of the compounds known as [*] (including any clinical materials containing such compounds), other than such amounts that Janssen needs to retain for regulatory purposes. The Materials shall be transferred within a reasonably practicable time after the written request of Metabolex. It is the expectation of the Parties that prior to [*], Metabolex shall only request the transfer of Materials that it needs in order to [*]. All Materials provided by Janssen and/or its Affiliates under this Agreement will be used by Metabolex only for the specific research and development purposes as disclosed and as permitted under the applicable license rights granted under Section 2.1 and subject to all the other restrictions and obligations under this Agreement. Such Materials will not be used or delivered to or for the benefit of any Third Party except as otherwise permitted under this Agreement without the prior written consent of Janssen, and will be used in compliance with all applicable laws, rules and regulations. The Materials supplied under this Agreement must be used with prudence and appropriate caution in any experimental work because not all of their characteristics may be known. Except as expressly set forth herein, THE MATERIALS ARE PROVIDED "AS IS" AND WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE OR EXCEPT AS OTHERWISE PROVIDED IN THIS AGREEMENT ANY WARRANTY THAT THE USE OF THE MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY.

3.6 Regulatory Matters. At all times after the Effective Date, Metabolex shall own and maintain, at its own cost, all regulatory filings and Regulatory Approvals for PPAR-δ Products that Metabolex is developing or commercializing pursuant to this Agreement, including all INDs, CTAs, NDAs, and statistical analyses. As such, Metabolex shall be responsible for reporting all adverse drug reactions related to PPAR-δ Products to the appropriate regulatory authorities in the relevant countries, in accordance with the applicable laws and regulations of such countries. As soon as practicable, but not more than thirty (30) days after the Effective Date, Janssen shall transfer ownership of, and all files relating to, its regulatory filings and associated with PPAR-δ Products to Metabolex (including, but not limited to, any INDs Controlled by Janssen or its Affiliates). Metabolex shall provide Janssen with copies of the draft

registration submissions in connection with obtaining Regulatory Approval for a PPAR-δ Product in the Major Markets, prior to their submission, and Janssen shall have the right to review such draft submission and provide comments thereon to Metabolex, which Metabolex agrees to reasonably consider. Janssen also agrees to discuss and answer any questions relating to PPAR-δ Know-How that Metabolex may have regarding regulatory matters for PPAR-δ Products. Metabolex shall also be responsible for all meetings with regulatory authorities and all post-approval commitments. Notwithstanding the above, Janssen shall prepare and file a FDA regulatory submission covering the [*]. Janssen shall provide Metabolex with a copy of the draft submission prior to its submission, and Metabolex shall review such draft submission and provide comments thereon to Janssen, which Janssen agrees to consider and incorporate into the submission if in Janssen's reasonable judgment such suggestions are justified and proper.

3.7 Commercialization of PPAR-δ Products. Metabolex will plan, control, carry out and fund all activities related to the promotion, marketing and sale of any PPAR-δ Products. Metabolex shall use Diligent Efforts to market, promote and commercialize any and all PPAR-δ Products as to which Regulatory Approval has been achieved in a Major Market provided that such commercial launch is commercially reasonable given label and pricing issue. Prior to launch of any PPAR-δ Product and from time to time thereafter (but no less frequently than annually), Metabolex will provide Janssen with updates on marketing activities relating to PPAR-δ Products.

3.8 Commercialization Costs. Metabolex shall be responsible for all costs and expenses associated with its commercialization activities, including manufacturing of PPAR-δ Products.

3.9 Right of First Negotiation.

(a) Right of First Negotiation. Metabolex hereby grants to Janssen a right of first negotiation under the terms of this Section 3.9 (the "**Right of First Negotiation**") to license a particular PPAR-δ Product or Other Product from Metabolex in the event that Metabolex elects to seek a Third Party corporate partner for the research, development, promotion, and/or commercialization of such PPAR-δ Product or Other Product.

(b) Notice; Exercise. In the event that Metabolex decides to seek a partner for the research, development, promotion, and/or commercialization of a PPAR-δ Product or Other Product, Metabolex shall provide notice in writing (the **"Notice to Partner**") to Janssen of such intention. Within thirty (30) days of receipt of such Notice to Partner, Janssen shall submit a reasonable due diligence request to Metabolex ("**Diligence Request**") in order for Janssen to evaluate Janssen's interest in such PPAR-δ Product or Other Product (as the case may be). Janssen shall then have thirty (30) days from the date of receipt of either (i) Metabolex's detailed answer to the Diligence Request (which answer may be provided by Metabolex allowing appropriate Janssen employees access to a facility having the Metabolex Information that is responsive to such Diligence Request and reasonable time to review such Information), or (ii) the Notice to Partner, if no such Diligence Request was timely submitted by Janssen (as applicable), to notify Metabolex in writing of its desire to exercise the PPAR-δ Right of First Negotiation (the

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"**Exercise**"). After receipt of Janssen's timely Exercise, the Parties shall then negotiate in good faith, for up to [*] after the date of such Exercise, the terms of an agreement (the **"PPAR-δ License Agreement"**) under which Janssen would receive an exclusive license to the PPAR-δ Product or Other Product (as the case may be) on commercially reasonable terms, taking into account the stage of development of the PPAR-δ Product or Other Product at the time of such negotiations and Metabolex's prior efforts and resources expended in developing the PPAR-δ Product or Other Product.

(c) Failure to Reach Agreement. If the Parties do not enter into the License Agreement within [*] after the date of the Notice to Partner, then Metabolex shall have no further restrictions or obligations vis-à-vis Janssen with respect to the applicable PPAR-δ Product or Other Product under this Section 3.9, and Metabolex shall be free to enter into a license, collaboration, joint venture or other agreement with a Third Party covering such PPAR-δ Product or Other Product (a "**Third Party Agreement**") at its discretion.

(d) Failure to Consummate Partnering Transaction. If Metabolex does not execute, within [*] after the expiration of the [*] period contemplated in Section 3.9(b), a definitive Third Party Agreement with a Third Party, then the Right of First Negotiation would then again apply if Metabolex subsequently seeks to partner such PPAR-δ Product or Other Product.

(e) Independent Development. Subject to Section 2.7(a), Metabolex and its Affiliates shall at all times retain the right, at its discretion, to develop and commercialize any PPAR-δ Product or Other Product independently.

3.10 Replacement Product.

(a) Metabolex shall have the option (the "**Replacement Product Option**") to discontinue its development of the PPAR-δ Compounds and PPAR-δ Products and select [*] as a Replacement Compound (as defined below), which option shall become exercisable on the Effective Date and shall terminate on [*].

(b) In the event Metabolex exercises the Replacement Product Option, such Replacement Compound (and any applicable product) shall be subject to the terms and conditions set forth in this Agreement in the same manner as a PPAR-δ Compound (and associated PPAR-δ Product) and all other terms and obligations accordingly modified, including without limitation, the representations and warranties in Section 7.2. Without limiting the generality of the foregoing, the terms PPAR-δ Compound, PPAR-δ Know-How, PPAR-δ Patent, and PPAR-δ Product shall be replaced with appropriate acronyms and definitions relating to such replacement product, as follows:

(i) "**Replacement Compound**" means the composition known as [*] as described in **Exhibit E**.

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(ii) "**Replacement Know-How**" means all Information that is Controlled by Janssen or its Affiliates as of the Effective Date and relates to the Replacement Compound, or is otherwise necessary for the development, manufacture, promotion, or use of the Replacement Compound, but excluding the Replacement Patents. For clarity, Replacement Know-How shall include the Product Data Package.

(iii) "**Replacement Patents**" means all Patents that are Controlled during the Term by Janssen or a Janssen Affiliate and that include one or more claims that claim or cover the Replacement Compound, or the manufacture or use of the Replacement Compound, including without limitation those listed on **Exhibit F**. In addition, "Replacement Patents" shall include all Patents that are Controlled, as of the date the option is exercised, by Janssen or a Janssen Affiliate to the extent that such Patents include one or more claims that claim or cover the formulation, manufacture or use of the Replacement Compound as it exists as of the date the option is exercised.

(iv) "**Replacement Product**" means any pharmaceutical product that contains the Replacement Compound, and including all formulations, line extensions and modes of administration thereof.

(c) In addition, in the event Metabolex exercises the Replacement Product Option, Section 2.7 shall be deleted in its entirety and replaced with the following;

(i) Metabolex. Metabolex hereby covenants that Metabolex and its Affiliates shall not [*] any [*] product (other than a Replacement Product) for the period of [*].

(ii) Metabolex Sublicensees. Metabolex hereby covenants that any sublicense related to the [*] of a Replacement Product that Metabolex or its Affiliates grant under this Agreement shall include a covenant by the sublicensee that such sublicensee shall not [*] any [*] product (other than a Replacement Product) for the period of [*]. Metabolex hereby agrees to use reasonable efforts to enforce such covenant [*] if it, or its Affiliates, become aware of a breach or anticipated breach of such covenant by any sublicensee.

(iii) Janssen. Janssen hereby covenants that Janssen and its Affiliates shall not [*] any [*] product for the period of [*].

(d) In the event Metabolex exercises the Replacement Product Option, all rights with respect to the PPAR-δ Patents and PPAR-δ Know-How shall revert back to Janssen and the terms of Section 9.5 (without giving effect to the replacement of terms contemplated by Section 3.10(b)) shall apply to the PPAR-δ Products and PPAR-δ Compounds.

ARTICLE 4

PAYMENTS

4.1 Royalties.

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(a) Royalty Percentage. For the term specified in Section 4.1(b), Metabolex shall pay to Janssen a running royalty equal to eight percent (8%) of Net Sales; *provided, however*, that the royalties owed to Janssen on Net Sales attributable to [*] shall [*] and [*]; *provided, further,* that the royalties owed to Janssen on Net Sales attributable to [*] shall not [*]. For the purpose of this Section 4.1(a), the [*] on Net Sales shall be equal to [*] plus [*] as a result of such Net Sales [*].

(b) Royalty Term. Metabolex's royalty obligations under this Section 4.1 as to a particular PPAR-δ Product in a particular country shall be in effect from the First Commercial Sale in the country and shall expire, on a country-by-country basis, on the later of (i) [*] years following the First Commercial Sale of such PPAR-δ Product in such country and (ii) the expiration of the last to expire Valid Claim of a PPAR-δ Patent covering such PPAR-δ Compound or PPAR-δ Product, or its manufacture or use in such country. Notwithstanding the foregoing, Metabolex shall be obligated to pay the royalties set forth in Section 4.1(a) on sales of a PPAR-δ Product in any country where such PPAR-δ Product [*] at the time [*].

4.2 Royalty Reductions.

(a) Janssen shall be solely responsible for all costs and expenses of any licenses between a Third Party and Janssen or its Affiliates in effect as of the Effective Date related to the PPAR-δ Products. If a Patent or Patents of a Third Party should exist in any country during the Term covering the development, manufacture, use or sale of any PPAR-δ Product, and which Metabolex believes in Metabolex's reasonable judgment impractical or impossible for Metabolex or any Affiliate or sublicensee to engage in the activity or activities licensed under this Agreement without obtaining a royalty bearing license from such Third Party under such Patent or Patents in a particular country, then Metabolex shall be entitled to a credit, against the royalty payments due to Janssen upon sales of such PPAR-δ Product in the applicable country, of an amount equal to [*] the royalty paid to such Third Party based upon the sales of the PPAR-δ Product in such country, but provided that such credit shall not exceed [*] the royalty otherwise payable to Janssen in the absence of such royalty offset.

(b) If (i) [*] generic products or [*] equivalent (in either case, "**Generic Products**") are sold by Third Parties in a country where Metabolex is selling a PPAR-δ Product, (ii) the Generic Products each contain the PPAR-δ Compound in the PPAR-δ Product, or any [*] of such PPAR-δ Compound; and (iii) sales of the Generic Products [*] in such country [*], the royalty owed under Section 4.1 for such PPAR-δ Product shall be determined under the following formula: The contribution of sales of such PPAR-δ Product in such country shall be reduced by [*] when calculating aggregate Metabolex Net Sales, but only for so long as the conditions set forth in subclauses (i), (ii), and (iii) continue to be satisfied.

4.3 Timing of Payment. Royalties obligations under Section 4.1 shall accrue at the time the sale of the royalty-bearing product is made, or invoice is delivered, whichever is earliest, and royalty or other payment obligations that have accrued during a particular calendar quarter shall be paid, on a quarterly basis, within forty-five (45) days after the end of the calendar quarter during which the obligation accrued. For clarity, Metabolex's obligation to pay royalties under this Agreement is imposed only once with respect to the same unit of PPAR-δ Product regardless of the number of Patents pertaining thereto.

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4.4 Sublicenses. In the event Metabolex grants licenses or sublicenses to others to sell PPAR-δ Products that are subject to royalties under Section 4.1, such licenses or sublicenses shall include an obligation for the sublicensee to account for and report its sales of PPAR-δ Products on the same basis as if such sales were sales by Metabolex, and Metabolex shall pay to Janssen, with respect to such sales, such royalties and payments as if such sales of the sublicensee were sales of Metabolex.

4.5 Mode of Payment. All payments to a Party hereunder shall be made by deposit of U.S. Dollars by wire transfer in immediately available funds in the requisite amount to such bank account as such Party may from time to time designate by notice to the other Party. With respect to sales outside the U.S., royalty and other sales-based amounts owed shall first be calculated in the currency of sale, and then such amounts shall be converted into U.S. Dollars using the average exchange rates as calculated and utilized by Metabolex's reporting systems and published accounts as used throughout Metabolex' business.

4.6 Royalty Reports and Records Retention. Within forty-five (45) days after the end of each calendar quarter during which PPAR-δ Products have been sold, Metabolex shall deliver to Janssen a written report of the amount of gross sales of each PPAR-δ Product in each country during the applicable calendar quarter, an itemized calculation of Net Sales, consistent with Metabolex's normal and customary reporting procedure, and a calculation of the amount of royalty payment due on such sales during such calendar quarter. For three (3) years after each sale of each PPAR-δ Product, Metabolex shall keep (and shall ensure that its Affiliates and sublicensees shall keep) complete and accurate records of such sale in sufficient detail to confirm the accuracy of the royalty and other payment calculations hereunder.

4.7 Audits.

(a) Upon the written request of Janssen, and not more than once in each calendar year, Metabolex shall permit an independent certified public accounting firm of internationally recognized standing selected by Janssen, and reasonably acceptable to Metabolex, to have access to and to review, during normal business hours and upon no less than thirty (30) days prior written notice, the applicable records of Metabolex and its Affiliates to verify the accuracy and timeliness of the reports and payments made by Metabolex under this Agreement. Such review may cover the records for sales made in any calendar year ending not more than thirty-six (36) months prior to the date of such request. The accounting firm shall disclose to Janssen only whether the royalty reports are correct or incorrect and the specific details concerning any discrepancies.

(b) If such accounting firm concludes that any payments were late or additional amounts were owed during such period, Metabolex shall pay the late payments and/or additional amounts, with interest from the date originally due as set forth in Section 4.8, within thirty (30) days after the date Janssen delivers to Metabolex a notice referencing the accounting

firm's written report and requesting such payment. If the amount of the underpayment is greater than [*] of the total amount actually owed for the period audited, then Metabolex shall in addition reimburse Janssen for all reasonable costs related to such audit; otherwise, Janssen shall pay all costs of the audit. In the event of overpayment, any amount of such overpayment shall be fully creditable against amounts payable for the immediately succeeding calendar quarter(s); provided, however, that if the overpayment exceeds [*], then such credit cannot be applied to reduce the amounts payable by Metabolex to Janssen for any particular calendar quarter by more than [*] of the amount otherwise due to Janssen.

(c) Metabolex shall include in each distribution agreement or sublicense granted by it pursuant to this Agreement a provision requiring the distributor or sublicensee to make reports to Metabolex, to keep and maintain records of sales made pursuant to such distribution agreement or sublicense and to grant access to such records by Janssen's independent accountant to the same extent required by Metabolex under this Agreement.

(d) Janssen shall (i) treat all information that it receives under this Section 4.7 or under any sublicense agreement of Metabolex in accordance with the confidentiality provisions of Article 6 of this Agreement and (ii) cause its accounting firm to enter into an acceptable confidentiality agreement with Metabolex obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement, in each case except to the extent necessary for Janssen to enforce its rights under the Agreement.

4.8 Interest. If either Party fails to make any payment due to the other Party under this Agreement, then interest shall accrue on a daily basis at an annual rate of [*] above the then-applicable prime commercial lending rate of Citibank, N.A. San Francisco, California, or at the maximum rate permitted by applicable law, whichever is the lower. Notwithstanding the foregoing, the interest shall only accrue on payments actually owed, from the original due date until payment made. If the Parties have a dispute regarding the results of the audit, they shall resolve the dispute through the mechanisms set forth in Section 10.9 below.

4.9 Taxes.

(a) Metabolex will make all payments to Janssen under this Agreement without deduction or withholding for taxes except to the extent that any such deduction or withholding is required by applicable law to be made on account of Taxes (as defined in Section 4.9(e)).

(b) Any tax required to be withheld under applicable law on amounts payable under this Agreement will promptly be paid by Metabolex on behalf of Janssen to the appropriate governmental authority, and Metabolex will furnish Janssen with proof of payment of such tax. Any such tax required to be withheld will be an expense of and borne by Janssen.

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(c) Metabolex and Janssen will cooperate with respect to all documentation required by any taxing authority or reasonably requested by Metabolex to secure a reduction in the rate of applicable withholding taxes.

(d) If Metabolex had a duty to withhold taxes in connection with any payment it made to Janssen under this Agreement but Metabolex failed to withhold, and such taxes were assessed against and paid by Metabolex, then Janssen will reimburse Metabolex for such taxes (including interest but excluding penalties), upon delivery by Metabolex of the documents evidencing Metabolex payment of the taxes and the basis for such payment. If Metabolex makes a claim under this Section 4.9(d) it will comply with the obligations imposed by Section 4.9(b) as if Metabolex had withheld taxes from a payment to Janssen.

(e) Solely for purposes of this Section 4.9, "**Tax**" means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including interest, penalties and additions thereto) that are imposed by the applicable federal government or other taxing authority.

ARTICLE 5

PATENTS

5.1 Patent Prosecution.

(a) Janssen will have the sole (except as otherwise provided below), responsibility, [*] for the preparation, filing, prosecution and maintenance of, and conducting or defending any interferences or similar proceedings and in obtaining and maintaining any patent extensions, supplementary protection certificates and the like with respect to, the PPAR-δ Patents. [*] Janssen will keep Metabolex informed of the progress with regard to all activities relating to the Janssen patent prosecution, including providing to Metabolex copies of all proposed filings and patent office responses and of all office actions and other material communications from patent offices relating to such prosecution efforts a reasonable time in advance of any proposed filing or required response, and Metabolex will have the right to comment on any such filings and responses. Janssen will consider in good faith the timely received requests and suggestions of Metabolex with respect to such filings or responses and Metabolex' strategies for Janssen patent prosecution. During [*], Janssen shall not discontinue the filing, prosecution or maintenance of any PPAR-δ Patent in a Major Market without Metabolex's prior written consent.

(b) Subject to the last sentence of Section 5.1(a), if Janssen intends to abandon or not maintain any PPAR-δ Patent and Janssen is not abandoning such PPAR-δ Patent in favor of another PPAR-δ Patent, Janssen will provide reasonable prior written notice to Metabolex of such intention to abandon (which notice will, in any event, [*] prior to the next deadline for any action that may be taken with respect to such Patent with the U.S. Patent & Trademark Office or any applicable foreign patent office) and, unless Janssen reasonably believes prosecution by Metabolex could have a material adverse impact on other patent applications or patents owned or

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Controlled by Janssen, then Janssen shall provide Metabolex the opportunity to assume responsibility for prosecuting and maintaining such PPAR-δ Patent. The foregoing sentence shall not apply to any patent application or patent for which Janssen does not have the right to grant to Metabolex such rights. In the event that Metabolex, in its sole discretion, elects to assume responsibility for prosecuting and maintaining such PPAR-δ Patent, then [*] such PPAR-δ Patent will then be deemed [*] for all purposes of this Agreement.

5.2 Common Interest Disclosures. With regard to any information or opinions disclosed pursuant to this Agreement by one Party to each other regarding intellectual property and/or technology owned by Third Parties, Metabolex or Janssen (or its Affiliates), Metabolex and Janssen agree that they have a common legal interest in determining whether, and to what extent, third party intellectual property rights may affect the conduct of the development, manufacturing, marketing and/or sale of PPAR-δ Products, and have a further common legal interest in defending against any actual or prospective Third Party claims based on allegations of misuse or infringement of intellectual property rights relating to the development, manufacturing, marketing and/or sale of PPAR-δ Products. Accordingly, Metabolex and Janssen agree that all such information and materials obtained by Metabolex and Janssen from each other will be used solely for purposes of the Parties' common legal interests with respect to the conduct of the Agreement. All information and materials will be treated as protected by the attorney-client privilege, the work product privilege, and any other privilege or immunity that may otherwise be applicable. By sharing any such information and materials, neither Party intends to waive or limit any privilege or immunity that may apply to the shared information and materials. Neither Party shall have the authority to waive any privilege or immunity on behalf of the other Party without such other Party's prior written consent, nor shall the waiver of privilege or immunity resulting from the conduct of one Party be deemed to apply against any other Party.

5.3 Enforcement of PPAR-δ Patents.

(a) Notice. The Parties shall promptly inform each other of any information that comes to their attention involving actual or apparent infringements or misappropriations by any Third Party of any PPAR-δ Patent or PPAR-δ Know-How used in connection with this Agreement.

(b) PPAR-δ Patents. If any PPAR-δ Patent is infringed by a Third Party in any country, in connection with the manufacture, use, importation, offer for sale, or sale in such country of a compound that is a PPAR-δ Compound, which manufacture, use or sale is likely to have a material adverse effect on current or future sales of any PPAR-δ Product being researched, developed or commercialized by Metabolex or its Affiliates or sublicensees (a "**Field Infringement**"), Metabolex shall have the first right, but not the obligation, to bring an action or suit with respect to such Field Infringement at its own expense using counsel chosen by Metabolex, and approved by Janssen, which approval shall not be unreasonably withheld. In any such action or suit involving a PPAR-δ Patent, Janssen shall have the opportunity to review any pleadings and provide comments with respect to such pleadings, which comments shall be reasonably considered by Metabolex. If requested by Janssen in writing, Metabolex will allow Janssen to join as a party in such action or suit, to the extent permitted by law, and in such regard Janssen may have

counsel of its choosing and at its expense to represent its interest in such action or suit, but Metabolex will control the conduct of the action or suit, and Janssen shall not bring any claim against Metabolex based on the conduct of such action or suit. If Metabolex does not choose to commence such action within [*] after Metabolex becomes aware of such Field Infringement ([*] in the event of receiving a Paragraph IV Certification as described in 21 C.F.R. §314.50(i)(1)(i)(A)(4)), then Janssen may, at its discretion, choose to bring an action or suit at Janssen's own expense. In any such action or suit brought by Janssen, Metabolex will have the right, at its own expense, to be represented in any such action by counsel of its own choice, but shall not have any right to control or interfere with Janssen's conduct of the suit or action. In no event shall Janssen notify any Third Party of any alleged Field Infringement or bring any suit or other action against any Third Party seeking to enforce any PPAR-δ Patents against any alleged Field Infringement (or otherwise), without first obtaining Metabolex's prior written consent. Janssen will have the sole and exclusive right and discretion (i) to defend or otherwise respond to any alleged invalidity or unenforceability of a PPAR-δ Patent, unless Janssen provides Metabolex such right or (ii) to bring an action or suit against or otherwise respond to Third Party activity that allegedly infringes a PPAR-δ Patent, that is not a Field Infringement. Notwithstanding the foregoing, in any such action or suit involving a PPAR-δ Patent, Metabolex shall have the opportunity to review any pleadings and provide comments with respect to such pleadings, which comments shall be reasonably considered by Janssen.

(c) Settlement. The Party bringing suit under this Section 5.3 shall keep the other Party reasonably informed as to the progress of the suit and all settlement discussions. A settlement or consent judgment or other voluntary final disposition of a suit brought by a Party under this Section may not be entered into without the prior written consent of the other Party (which consent shall not be unreasonably withheld or delayed); provided, however, that such settlement, consent judgment or other disposition does not admit the invalidity or unenforceability of any Patent; and provided further, that any rights to continue the infringing activity in such settlement, consent judgment or other disposition shall be limited to the product or activity that was the subject of the suit.

(d) Recovery. Except as otherwise agreed to by the Parties as part of a cost-sharing arrangement, any recovery realized by a Party as a result of a litigation or other action with respect to a Field Infringement will first be applied to reimburse Metabolex for any actual litigation costs and expenses borne by Metabolex and not yet reimbursed by Janssen, and Janssen for any actual litigation costs and expenses borne by Janssen (including amounts paid to Metabolex to reimburse Metabolex for its litigation costs), and any amounts remaining after such reimbursement (a "**Net Recovery**") will be shared by the Parties as follows: (i) if recovered by Metabolex, Metabolex will retain [*] of such Net Recovery and pay Janssen [*] of such Net Recovery [*] of receipt of payment, or (ii) if recovered by Janssen, Janssen will retain [*] of such Net Recovery and pay Metabolex [*] of such Net Recovery [*] of receipt of payment. Janssen will have the sole right to bring and control, and to retain all recovery from, any action or proceeding with respect to infringement of any PPAR-δ Patent at its own expense and by counsel of its own choice with respect to any activities by a Third Party that are not Field Infringements.

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(e) Assistance. In the event of any patent infringement litigation involving a PPAR-δ Product and any Patent, the non-prosecuting or non-defending Party shall render such reasonable assistance as may be requested by the prosecuting or defending Party in connection with such infringement actions. If one Party requests the other Party's reasonable assistance in connection with such infringement claims or actions, the requesting Party shall reimburse the other Party for such direct, documented out-of-pocket expenses as are reasonably incurred during the course of its providing such requested assistance. Before incurring such expenses, the Parties shall in good faith agree on the nature and extent of assistance to be rendered. The non-prosecuting or non-defending Party agrees to be joined as a party plaintiff, at the other Party's expense, in any such action if necessary for such other Party to have standing to bring or continue an infringement action hereunder. If a PPAR-δ Patent is licensed-in to Janssen, Janssen agrees to use reasonable commercial efforts to obtain the licensor's consent to sue under such licensed-in Patent.

5.4 Cooperation by Metabolex and Janssen in Patent and Regulatory Filings. The Parties shall cooperate in order to avoid loss of any rights that may otherwise be available to the Parties under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, the Supplementary Certificate of Protection of the Member States of the European Union and other similar measures in any other country. Without limiting the foregoing, Metabolex shall notify Janssen upon receipt of Regulatory Approval to market a PPAR-δ Compound or PPAR-δ Product in the U.S., and timely supply Janssen with all information necessary to file an application for patent term extension for a relevant PPAR-δ Patent within the required period following Regulatory Approval. The Parties shall, if necessary and appropriate use reasonable efforts to agree upon a joint strategy relating to patent term extension, but in the absence of mutual agreement with respect to such extension issue, Metabolex shall make the final decision on which Patent and/or the claims of the Patent will be selected for patent term extension. The obligations set forth in this Section 5.4 shall apply with respect to patent term extensions, or the equivalent, in any other country. Any application for patent term extension in the U.S. shall be made by the Party who Controls the relevant patent.

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ARTICLE 6

CONFIDENTIALITY

6.1 Confidentiality Obligations. All Information disclosed by one Party to the other Party pursuant to this Agreement and all Information relating to a PPAR-δ Compound disclosed pursuant to the Confidentiality Agreements entered into by and between Affiliates of Janssen and Metabolex dated [*] (as amended) and [*], shall be "**Confidential Information**" of the disclosing Party for all purposes hereunder. Each Party agrees that, for the Term and for [*] years thereafter, such Party shall, and shall ensure that its officers, directors, employees and agents shall, keep completely confidential (using at least the same standard of care as it uses to protect proprietary or confidential information of its own, but in no event less than reasonable care) and not publish or otherwise disclose and not use for any purpose except as expressly permitted hereunder any Confidential Information furnished to it by the other Party (including, without limitation, know-how of the disclosing Party). The foregoing obligations shall not apply to any Information disclosed by a Party hereunder to the extent that the receiving Party can demonstrate with competent evidence that such Information:

(a) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) was subsequently lawfully disclosed to the receiving Party or its Affiliate by a Third Party other than in contravention of a confidentiality obligation of such Third Party to the disclosing Party; or

(e) was developed or discovered by employees of the receiving Party or its Affiliates who had no access to the Confidential Information of the disclosing Party.

6.2 Authorized Disclosure. A Party may disclose the Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following instances:

(a) Filing or prosecuting Patents relating to PPAR-δ Products as permitted under this Agreement;

(b) Regulatory filings relating to PPAR-δ Products;

(c) Prosecuting or defending litigation as permitted under this Agreement;

(d) Disclosure, in connection with the performance of this Agreement, to Affiliates, sublicensees, research collaborators, employees, consultants, subcontractors or agents, each of whom prior to disclosure must be bound by similar obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article 6.

Further, a Party may disclose the other Party's Confidential Information to the extent such disclosure is required by valid court order or legal process, provided that such Party gives the other Party advance notice of such required disclosure, limits the disclosure to that actually required, and cooperates in the other Party's attempts to obtain a protective order or confidential treatment of the information required to be disclosed.

6.3 Confidentiality of Agreement Terms. The Parties acknowledge that the terms of this Agreement shall be treated confidentially as Confidential Information of both Parties. Notwithstanding the foregoing, such terms may be disclosed by a Party to investment bankers, investors, and potential investors or acquirers, in the context of a potential transaction, each of

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whom prior to disclosure must be bound by similar obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article 6. A copy of this Agreement may be filed with the Federal Trade Commission or the Justice Department for HSR review. In addition, a copy of this Agreement may be filed by a Party with the Securities and Exchange Commission, The New York Stock Exchange and/or the Nasdaq National Market as required by applicable law or regulation. In connection with any such filing, such Party shall endeavor to obtain confidential treatment of economic and trade secret information. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information except as permitted hereunder.

6.4 Publicity. Upon the execution of this Agreement, Metabolex may issue a press release announcing the execution of this Agreement, the text of which is set forth in an Exhibit to the PPAR-γ License Agreement. After such initial press release, Metabolex may make periodic press releases or other public disclosures relating to the Agreement or developments under the Agreement at its discretion. Metabolex shall not disclose the Confidential Information of Janssen in any press release and shall not use the name of Janssen or any Janssen Affiliate in any press release, in each case without the prior written approval of Janssen. Janssen and its Affiliates shall not issue a press release or public announcement relating to the PPAR-δ Product or this Agreement without the prior written approval of Metabolex, which approval shall not be unreasonably withheld or delayed.

6.5 Publications. Metabolex and its Affiliates and sublicensees shall be free to publish or present the results of any research or development carried out under this Agreement, provided that Metabolex shall provide Janssen the opportunity for prior review and comment on any such publication to the extent it would disclose specific, proprietary Confidential Information of Janssen. In such latter case, Metabolex would provide Janssen the opportunity to review any proposed abstracts, manuscripts or presentations (including verbal presentations) that contain specific, proprietary Confidential Information of Janssen at least thirty (30) days prior to its intended submission for publication, and to reasonably consider deleting such Confidential Information at Janssen's reasonable request.

ARTICLE 7

REPRESENTATIONS AND WARRANTIES

7.1 Representations and Warranties. Each Party represents and warrants to the other Party that, as of the Execution Date:

(a) such Party is duly organized and validly existing under the laws of the state or jurisdiction of its incorporation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

(b) such Party has taken all corporate action necessary to authorize the execution and delivery of this Agreement and the performance its obligations under this Agreement;

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(c) this Agreement is a legal and valid obligation of such Party, binding upon such Party and enforceable against such Party in accordance with the terms of this Agreement, except as enforcement may be limited by applicable bankruptcy or other debtor's rights laws and regulations. The execution, delivery and performance of this Agreement by such Party does not violate any agreement or instrument to which such Party is a party or by which such Party is bound, and does not violate any law or regulation of any court, governmental body or administrative or other agency having authority over such Party. All consents, approvals and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained, or will be obtained on or prior to the Effective Date;

(d) it has the full right, power and authority to enter into this Agreement, and to perform its obligations hereunder; and

(e) has independently in good faith determined whether or not notification is required under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and will file such notification if deemed necessary.

7.2 Janssen Warranties. Janssen represents and warrants that:

(a) **Exhibit C** accurately identifies all Patent rights Controlled by Janssen as of the Execution Date that claim a PPAR-δ Compound, PPAR-δ Product or its manufacture or use;

(b) as of the Execution Date it has not granted any right, license or interest in or to the PPAR-δ Patents or PPAR-δ Know-How that is in conflict with the rights and licenses granted to Metabolex under this Agreement; and

(c) as of the Execution Date, other than Third Party allegations disclosed to Metabolex with respect to the Replacement Patents, it owns or has a license to the PPAR-δ Patents and PPAR-δ Know-How and has the ability to grant to Metabolex the licenses thereunder as granted in this Agreement.

7.3 Neither Party makes any representation or warranty that development and marketing of PPAR-δ Product shall be the exclusive means by which such Party will participate in development, manufacture, use and/or sale of pharmaceutical products for treatment or prevention of metabolic syndrome, insulin resistance, diabetes, obesity, or dyslipidemia.

7.4 Disclaimer of Warranties. EXCEPT AS SET FORTH IN SECTIONS 7.1 AND 7.2, EACH PARTY EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT OF THIRD PARTY RIGHTS. IN PARTICULAR, THE PPAR-δ COMPOUNDS AND PPAR-δ PRODUCTS ARE PROVIDED "AS IS" AND WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING WITHOUT

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LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF PPAR-δ PRODUCTS WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY, OTHER THAN AS EXPRESSLY SET FORTH IN SECTION 7.2.

ARTICLE 8

INDEMNIFICATION

8.1 Indemnification by Metabolex. Metabolex shall indemnify, defend and hold Janssen and its Affiliates and each of their respective employees, officers, directors and agents (the "**Janssen Indemnitees**") harmless from and against any and all liability, damages, loss, cost or expense (including reasonable attorneys' fees) arising out of Third Party claims, actions, proceedings, or suits against an Janssen Indemnitee resulting from (a) Metabolex's performance or non-performance of its obligations under this Agreement; (b) the development, manufacture, use, importation, promotion or sale of PPAR-δ Products and/or PPAR-δ Compounds by Metabolex and/or its Affiliates, sublicensees, distributors, agents and customers; or (c) breach by Metabolex of its representations and warranties set forth in Article 7; *provided, however*, Metabolex's obligations pursuant to this Section 8.1 shall not apply to the extent such claims or suits result from the negligence or willful misconduct of any of the Janssen Indemnitees or breach by Janssen of its representations and warranties set forth in Article 7.

8.2 Indemnification by Janssen. Janssen shall indemnify, defend and hold Metabolex and its Affiliates and each of their respective agents, employees, officers and directors (the "**Metabolex Indemnitees**") harmless from and against any and all liability, damage, loss, cost or expense (including reasonable attorney's fees) arising out of Third Party claims or suits against a Metabolex Indemnitee resulting from (a) Janssen's performance or non-performance of its obligations under this Agreement; or (b) breach by Janssen of its representations and warranties set forth in Article 7; *provided, however*, that Janssen's obligations pursuant to this Section 8.2 shall not apply to the extent that such claims or suits result from the negligence or willful misconduct of any of the Metabolex Indemnitees or breach by Metabolex of its representations and warranties set forth in Article 7.

8.3 Notification of Claims; Conditions to Indemnification Obligations. As a condition to a Party's right to receive indemnification under this Article 8, it shall (a) promptly notify the other Party as soon as it becomes aware of a claim or action for which indemnification may be sought pursuant hereto, (b) cooperate with the indemnifying Party in the defense of such claim or suit, and (c) permit the indemnifying Party to control the defense of such claim or suit, including without limitation the right to select defense counsel, which counsel shall be reasonably satisfactory to the indemnified Party. In no event, however, may the indemnifying Party compromise or settle any claim or suit in a manner that admits fault or negligence on the part of the indemnified Party without the prior written consent of the indemnified Party. The indemnifying Party shall have no liability under this Article 8 with respect to claims or suits settled or compromised without its prior written consent.

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8.4 Insurance. Metabolex at its own expense, will maintain during the term of the Agreement clinical trial insurance in compliance with local regulations but in no event shall such coverage be in amounts less than [*] per occurrence. In addition, prior to any First Commercial Sale, Metabolex at its own expense, will maintain through termination of the Agreement and for a period of at least [*] years thereafter, product liability insurance in amounts not less than [*] per occurrence and [*] annual aggregate. Such insurance shall include worldwide coverage. Janssen agrees during the term of the Agreement and for a period of at least [*] years thereafter to maintain (a) workers' compensation insurance for all of its employees, the limits of which shall be as required under statute; (b) commercial general liability insurance having limits of not less than [*] in the aggregate and [*] per occurrence. Each Party shall provide evidence of insurance in accordance with this Section 8.4 to the other Party upon the request of the other Party.

ARTICLE 9

TERM; TERMINATION

9.1 Term and Expiration. The term of this Agreement shall commence upon the Effective Date and, unless earlier terminated pursuant to Section 9.2 or 9.3, shall expire on a country-by-country and PPAR-δ Product-by-PPAR-δ Product basis, upon the expiration of the royalty term as set forth in Section 4.1(b) as to such country with regard to such PPAR-δ Product. Thereafter, the licenses granted to Metabolex in Section 2.1 as to such PPAR-δ Product in such country shall survive but shall be non-exclusive, fully-paid and royalty-free.

9.2 Termination for Material Breach.

(a) If a Party breaches any of its material obligations under the Agreement, the Party not in default may give to the breaching Party a written notice specifying the nature of the default, requiring it to make good or otherwise cure such breach, and stating its intention to terminate this Agreement if such breach is not cured. Subject to Section 10.12 of this Agreement, if such breach is not cured within [*] (or [*] with respect to breach of a payment obligation) after the receipt of such notice, the Party not in default shall be entitled, without prejudice to any of its other rights conferred under this Agreement, and in addition to any other remedies available to it by law or in equity, to terminate this Agreement by written notice to the other Party.

(b) The right of a Party to terminate this Agreement, as herein above provided, shall not be affected in any way by its waiver or failure to take action with respect to any prior default or breach.

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9.3 Termination by Metabolex. Metabolex may terminate this Agreement in its entirety for any reason or no reason upon at least [*] prior written notice to Janssen.

9.4 "Anti-Shelving" Provision.

(a) If Metabolex does not expend more than a de minimus amount of effort and resources on the research and/or development of at least one (1) PPAR-δ Product for any period of [*] or more, then (regardless of whether such failure constitutes a failure to expend Diligent Efforts) Janssen shall have the right to terminate this Agreement on written notice with respect to all PPAR-δ Products, provided that Metabolex does not commence and thereafter continue to expend a material amount of effort and resources on the research and/or development of at least one (1) PPAR-δ Product within [*] of such written notice by Janssen. This Section 9.4(a) shall automatically terminate at such time as Metabolex (or its Affiliate or sublicensee) has [*] on a PPAR-δ Product.

(b) Notwithstanding Section 9.4(a), Janssen shall not have the right to terminate this Agreement pursuant to Section 9.4(a) if Metabolex has delayed development of its PPAR-δ Products due to either:

(i) financial constraints that have caused Metabolex to delay its PPAR-δ programs as well as a majority of its other programs; provided, however, that:

(1) Metabolex has provided written to notice to Janssen that it wishes to rely on this Section 9.4(b)(i);

(2) [*] the written notice described in Section 9.4(b)(i)(1); and

(3) Metabolex restarts development of its PPAR-δ Products within [*] after the conclusion of the [*] period of inactivity described in Section 9.4(a); or

(ii) safety or material technical or regulatory cause; provided, however, that Metabolex in good faith intends to continue development of its PPAR-δ Products as soon as practicable if and after the safety, technical and/or regulatory issues are resolved.

9.5 Consequences of Termination. If a Party terminates this Agreement pursuant to Section 9.2(a); Janssen terminates this Agreement pursuant to Section 9.4; or Metabolex terminates this Agreement pursuant to Section 9.3, then:

(a) Licenses to Janssen. Metabolex shall grant to Janssen a worldwide, exclusive (even as to Metabolex and its Affiliates), irrevocable, license (with full rights to sublicense) under the Metabolex Know-How and Metabolex Patents, to make, have made, import, use, offer for sale and sell PPAR-δ Products and PPAR-δ Compounds. Metabolex shall also grant to Janssen a worldwide, exclusive (even as to Metabolex and its Affiliates), irrevocable, license (with full rights to sublicense) under Patents that are Controlled as of the Effective Date by Metabolex or a Metabolex Affiliate to the extent that such Patents include one or more claims that claim or cover the composition of matter, formulation, manufacture or use of

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a PPAR-δ Compound or PPAR-δ Product as such exists on the date of termination, to make, have made, import, use, offer for sale and sell such PPAR-δ Compound and PPAR-δ Product (as such may be further developed and commercialized). Notwithstanding the foregoing, Janssen shall reimburse Metabolex for Third Party royalties and other out-of-pocket payments incurred by Metabolex as a result of any Third-Party obligations of Metabolex triggered by supplying such licenses to Janssen. Further, the licenses granted in this Section 9.5(a) shall be [*] to the extent such licenses [*] PPAR-δ Products and PPAR-δ Compounds. To the extent that such licenses [*] PPAR-δ Products and PPAR-δ Compounds, the licenses shall be [*] and shall be [*].

(b) Regulatory Filings. Metabolex shall assign to Janssen, and will provide full copies of, all Regulatory Approvals and INDs, NDAs and other similar regulatory applications that relate to PPAR-δ Products and/or PPAR-δ Compounds and are owned or Controlled by Metabolex or its Affiliates. Metabolex shall also take such actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights thereunder to Janssen.

(c) Data Disclosure. Metabolex will provide to Janssen copies of the relevant portions of all material reports and data, including clinical and non-clinical data and reports, obtained or generated by or on behalf of Metabolex or its Affiliates pursuant to this Agreement to the extent that they relate to PPAR-δ Products and PPAR-δ Compounds, within sixty (60) days of such termination unless otherwise agreed, and Janssen shall have the right to use any such Information in developing and commercializing PPAR-δ Products and PPAR-δ Compounds, and to license any Third Parties to do so.

(d) Trademarks. If Metabolex used with regard to any PPAR-δ Product or PPAR-δ Compound in a country any trademark, tradename or logo related solely to a PPAR-δ Product and/or PPAR-δ Compound (**"Metabolex PPAR-δ Product Mark(s)"**) Metabolex shall assign to Janssen, at Janssen's cost for the transactional documents and any governmental fees for effecting such assignment (upon written request from Janssen within one (1) year of such termination under this Section 9.5), the Metabolex PPAR-δ Product Mark(s). For clarity, Janssen shall under no circumstance receive any rights under the housemarks of Metabolex or its Affiliates, except with respect to selling off existing inventory.

(e) Third-Party Contracts. At Janssen's request, Metabolex shall promptly provide to Janssen copies of all Third-Party agreements with Metabolex or its Affiliates containing a license under Patents or patent applications claiming inventions or know-how specific to or used or incorporated into the development, manufacture and/or commercialization of the PPAR-δ Products and PPAR-δ Compounds. At Janssen's reasonable request, Metabolex shall reasonably cooperate with Janssen to make available to Janssen the benefits of such Third-Party agreements, at Janssen's expense.

(f) Further Sales. In the event of any such termination, Metabolex may continue to sell its remaining inventory of the PPAR-δ Product or PPAR-δ Compound for a period of [*] from the effective date of such termination, subject to the payment of royalties pursuant to Section 4.1. Metabolex covenants that promptly after such [*] period it and its Affiliates and former sublicensees hereunder shall cease to sell, and thereafter shall not sell, any PPAR-δ Products or PPAR-δ Compounds.

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(g) Remaining Materials. At the end of the period described in Section 9.5(f) or if this Agreement is terminated prior to the First Commercial Sale, at the request of Janssen, Metabolex shall transfer to Janssen, at a price to be agreed in good faith, which shall not be lower than [*] of Metabolex's manufacturing cost for the PPAR-δ Products and/or PPAR-δ Compounds or higher than [*] of Metabolex's manufacturing cost for the PPAR-δ Products and/or PPAR-δ Compounds, all quantities of PPAR-δ Products and/or PPAR-δ Compounds in the possession of Metabolex or its Affiliates (including, without limitation, clinical trial supplies and PPAR-δ Products and/or PPAR-δ Compounds intended for commercial sale).

(h) PPAR-δ Product/Compound Manufactured by Metabolex. If any PPAR-δ Product and/or PPAR-δ Compound was manufactured by Metabolex (including, without limitation, any testing and/or release) at the time of such termination, at Janssen's request, Metabolex shall continue to manufacture such PPAR-δ Product and/or PPAR-δ Compound for Janssen, unless such would be an undue burden on Metabolex, at a cost equal to [*] of Metabolex's manufacturing cost for the PPAR-δ Product and/or PPAR-δ Compound from the time of the effective date of termination, until such time (not to exceed [*]) as Janssen is able to secure an equivalent alternative commercial manufacturing source from which quantities of PPAR-δ Product and/or PPAR-δ Compound are registered for commercial sale in each country of the Territory; *provided, however*, that this Section 9.6(h) shall not be construed to require Metabolex to manufacture the PPAR-δ Product and/or PPAR-δ Compound beyond the capacity of Metabolex as of the date of termination and provided that this Section 9.5(h) shall not be construed to require Metabolex in its reasonable judgment to infringe any Patent of a Third Party for which it does not have an appropriate license.

(i) Technical Assistance. Promptly after the effective date of such termination, Metabolex shall provide, at Janssen's request and expense (at Metabolex's actual cost) technical assistance of the equivalent of up to a total of [*] full-time equivalent persons (i.e., a total not to exceed [*] of person-time), in the period from the effective date of such termination until [*] months after such date, to provide technology transfer necessary for Janssen to commence or continue to commercially manufacture PPAR-δ Products and/or PPAR-δ Compounds, and a non-exclusive, royalty-free, perpetual license under any Know-How disclosed by Metabolex to Janssen in the course of such activities to manufacture PPAR-δ Products and/or PPAR-δ Compounds.

(j) No Further Representations. Subject to Sections 9.5(f) and (h), Metabolex and its Affiliates shall (1) discontinue making any representation regarding its status as a licensee of or distributor for Janssen, for all PPAR-δ Products and/or PPAR-δ Compounds and (2) cease conducting any activities with respect to the marketing, promotion, sale or distribution of the PPAR-δ Products and/or PPAR-δ Compounds.

(k) Commercialization. Janssen shall have the sole right under the PPAR-δ Patents and PPAR-δ Know-How to develop and commercialize the PPAR-δ Products and/or

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PPAR-δ Compounds itself or with one or more Third Parties, and shall have the right, without obligation to Metabolex, to take any such actions in connection with such activities as Janssen (or its designee), at its discretion, deems appropriate.

(l) Other Consequences. Subject to Section 9.6 and this Section 9.5, each Party shall promptly return to the other Party all relevant records and materials in its possession or control containing or comprising the other Party's Confidential Information and to which the Party does not retain rights hereunder; *provided, however*, that each Party shall be entitled to retain copies of the other Party's Confidential Information to the extent necessary to comply with applicable regulatory obligations and shall be entitled to retain one copy of the other Party's Confidential Information for archival purposes; (ii) all licenses granted by each Party to the other under this Agreement shall terminate (except as set forth in this Section 9.5); (iii) all rights in any and all PPAR-δ Patents and PPAR-δ Know-How shall revert to Janssen, and (iv) any and all claims and payment obligations that accrued prior to the date of such termination shall survive such termination.

9.6 Accrued Rights; Surviving Obligations.

(a) Termination, relinquishment or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination, or expiration. Such termination, relinquishment or expiration shall not relieve a Party from obligations that are expressly indicated to survive termination or expiration of this Agreement.

(b) Without limiting the foregoing,

(i) Sections [*] of this Agreement shall survive the expiration or termination of this Agreement for any reason; and

(ii) Section [*] of this Agreement shall survive the expiration or termination of this Agreement for any reason but only to the extent relating to matters commenced, or facts occurring, prior to the date of termination or relating to obligations or rights set forth in this Article 9.

9.7 Rights in Bankruptcy. All licenses granted under this Agreement by Janssen are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(34A) of the U.S. Bankruptcy Code. The Parties agree that Metabolex, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against Janssen under the U.S. Bankruptcy Code, Metabolex shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property (including all Information related to such intellectual property and rights of reference with respect to Regulatory Approvals), and same, if not already in its possession, shall be promptly delivered to it (a) upon any such

commencement of a bankruptcy proceeding upon its written request therefore, unless Janssen continues to perform all of its obligations under this Agreement, or (b) if not delivered or granted under (a) above, following the rejection of this Agreement by or on behalf of Janssen upon written request therefore by Metabolex.

9.8 Consequences of Material Breach by Janssen. If Janssen breaches a material obligation under Section [*], Metabolex shall give Janssen a written notice specifying the nature of the default, requiring Janssen to make good or otherwise cure such breach, and stating its intention to terminate the rights specified below if such breach is not cured. Subject to Section 10.12 of this Agreement, if such breach is not cured within [*] (or [*] with respect to breach of a payment obligation) after the receipt of such notice, and Metabolex does not wish to terminate the Agreement in its entirety pursuant to Section 9.2(a), then Metabolex shall be entitled, without prejudice to any of its other rights conferred under this Agreement, and in addition to any other remedies available to it by law or in equity, to [*] and/or [*] under this Agreement, upon written notice to Janssen.

ARTICLE 10

MISCELLANEOUS PROVISIONS

10.1 Relationship of the Parties. Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency or employer-employee relationship between the Parties. Neither Party shall incur any debts or make any commitments for the other.

10.2 Assignments. Except as expressly provided herein, neither this Agreement nor any interest hereunder shall be assignable, nor any other obligation delegable, by a Party without the prior written consent of the other; *provided, however,* that a Party may assign this Agreement to any Affiliate or to any successor in interest by way of merger, acquisition or sale of all or substantially all of its assets provided that such successor agrees in writing to be bound by the terms of this Agreement as if it were the assigning Party. This Agreement shall be binding upon the successors and permitted assigns of the Parties. Any assignment not in accordance with this Section 10.2 shall be void. Notwithstanding the foregoing, in the event that a Party assigns this Agreement to its successor in interest by way of merger, acquisition, or sale of all or substantially all of its assets, the intellectual property rights of such successor in interest, and of any of its Affiliates as of just prior to such assignment, as existing immediately prior to the closing of such transaction, shall be automatically excluded from the rights licensed to the other Party under this Agreement.

10.3 Responsibility for Affiliates. Either Party may use one or more of its Affiliates to perform its obligations and duties hereunder; provided however, that each Party shall remain liable hereunder for the prompt payment and performance of all its obligations hereunder. To the extent that the rights granted to a Party hereunder are exercised by an Affiliate of such Party (or by any sublicensee of an Affiliate), such Affiliate or sublicensee shall be bound by the corresponding obligations of such Party. To the extent that this Agreement imposes obligations on Affiliates of a Party, such Affiliates shall perform such obligations and such Party shall be responsible for any failure of such Affiliate to perform such obligations.

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10.4 Further Assurances. Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other reasonable acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

10.5 Force Majeure. Neither Party shall be liable to the other for failure or delay in the performance of any of its obligations under this Agreement for the time and to the extent such failure or delay is caused by earthquake, riot, civil commotion, war, strike, flood, act of terrorism, governmental acts or restrictions or any other reason that is beyond the control of the respective Party. The Party affected by force majeure shall provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities), and will use Diligent Efforts to overcome the difficulties created thereby and to resume performance of its obligations as soon as practicable.

10.6 Entire Agreement of the Parties; Amendments. This Agreement and the attachments hereto constitute and contain the entire understanding and agreement of the Parties respecting the subject matter hereof and cancel and supersede any and all prior negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter (including the Confidentiality Agreement entered into by and between Affiliates of Janssen and Metabolex [*] and the addendums thereto); *provided, however*, the Four-Party Nondisclosure Agreement, by and among an Affiliate of Janssen, Metabolex and two Third Parties, dated [*], and a second Four-Party Nondisclosure Agreement, by and among an Affiliate of Janssen, Metabolex and two other Third Parties, dated [*] shall remain in force and effect in accordance with their terms. No waiver, modification or amendment of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

10.7 Captions. The captions to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement.

10.8 Applicable Law. This Agreement shall be governed by and interpreted in accordance with the laws of California, USA, excluding application of any conflict of laws principles that would require application of different law. Notwithstanding the above, any dispute regarding and limited to validity or enforceability of any patent shall be governed by the patent laws of the jurisdiction in which such patent was granted.

10.9 Disputes. In the event of any controversy or claim arising out of, relating to or in connection with any provision of this Agreement, or the rights or obligations of the Parties hereunder, the Parties shall try to settle their differences amicably between themselves. Either Party may initiate such informal dispute resolution by sending written notice of the dispute to the other Party, and within ten (10) days after such notice appropriate representatives of the Parties shall meet for attempted resolution by good faith negotiations. If such representatives are unable to resolve promptly such disputed matter, it shall be referred to the Chief Executive Officer of

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Metabolex and to the President of Janssen, for discussion and resolution. If such personnel are unable to resolve such dispute within thirty (30) days of initiating such negotiations, unless otherwise agreed by the Parties, such dispute shall be finally settled under Sections 10.10 and 10.11.

10.10 Mediation

(a) Any dispute, controversy or claim arising out of or related to this agreement, or the interpretation, application, breach, termination or validity thereof, including any claim of inducement by fraud or otherwise, which claim would, but for this provision, be submitted to arbitration shall, before submission to arbitration, first be mediated through non-binding mediation in accordance with the CPR Mediation Procedure then in effect of the CPR Institute for Dispute Resolution ("**CPR**") available at www.cpradr.org/m_proced.htm, except where that procedure conflicts with these provisions, in which case these provisions control. The mediation shall be conducted in San Francisco, CA and shall be attended by a senior executive with authority to resolve the dispute from each of the operating companies that are Parties.

(b) The mediator shall be neutral, independent, disinterested and shall be selected from a professional mediation firm such as ADR Associates or JAMS/ENDISPUTE or CPR.

(c) The Parties shall promptly confer in an effort to select a mediator by agreement. In the absence of such an agreement within ten (10) days of initiation of the mediation, the mediator shall be selected by CPR as follows: CPR shall provide the Parties with a list of at least fifteen (15) names from the CPR Panels of Distinguished Neutrals. Each Party shall exercise challenges for cause, two (2) peremptory challenges, and rank the remaining candidates within five (5) working days of receiving the CPR list. The Parties may together interview the three top-ranked candidates for no more than one hour each and, after the interviews, may each exercise one peremptory challenge. The mediator shall be the remaining candidate with the highest aggregate ranking.

(d) The mediator shall confer with the Parties to design procedures to conclude the mediation within no more than forty-five (45) days after initiation. Under no circumstances may the commencement of arbitration under Section 10.11 be delayed more than forty-five (45) days by the mediation process specified herein absent contrary agreement of the Parties.

(e) Each Party agrees not to use the period or pendency of the mediation to disadvantage the other Party procedurally or otherwise. No statements made by either side during the mediation may be used by the other or referred to during any subsequent proceedings.

(f) Each Party has the right to pursue provisional relief from any court, such as attachment, preliminary injunction, replevin, etc. to avoid irreparable harm, maintain the *status quo*, or preserve the subject matter of the arbitration, even though mediation has not been commenced or completed.

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10.11 Dispute Resolution

(a) Any dispute, claim or controversy arising from or related in any way to this Agreement or the interpretation, application, breach, termination or validity thereof, including any claim of inducement of this Agreement by fraud or otherwise, will be submitted for resolution to arbitration pursuant to the rules then pertaining of the CPR Institute for Dispute Resolution for Non-Administered Arbitration (available at www.cpradr.org/arb-rules.htm), or successor ("**CPR**"), except where those rules conflict with these provisions, in which case these provisions control. The arbitration will be held in San Francisco, CA.

(b) The panel shall consist of three (3) arbitrators chosen from the CPR Panels of Distinguished Neutrals (or, by agreement, from another provider of arbitrators) each of whom is a lawyer with at least fifteen (15) years experience with a law firm or corporate law department of over twenty-five (25) lawyers or who was a judge of a court of general jurisdiction. In the event the aggregate damages sought by the claimant are stated to be less than $5 million, and the aggregate damages sought by the counterclaimant are stated to be less than $5 million, and neither side seeks equitable relief, then a single arbitrator shall be chosen, having the same qualifications and experience specified above. Each arbitrator shall be neutral, independent, disinterested, impartial and shall abide by the CPR-Georgetown Commission Proposed Model Rule for the Lawyer as Neutral available at www.cpradr.org/cpr-george.html.

(c) The Parties agree to cooperate (1) to attempt to select the arbitrator(s) by agreement within forty-five (45) days of initiation of the arbitration, including jointly interviewing the final candidates, (2) to meet with the arbitrator(s) within forty-five (45) days of selection and (3) to agree at that meeting or before upon procedures for discovery and as to the conduct of the hearing which will result in the hearing being concluded within no more than nine (9) months after selection of the arbitrator(s) and in the award being rendered within sixty (60) days of the conclusion of the hearings, or of any post-hearing briefing, which briefing will be completed by both sides within forty-five (45) days after the conclusion of the hearings.

(d) In the event the Parties cannot agree upon selection of the arbitrator(s), the CPR will select arbitrator(s) as follows: CPR shall provide the Parties with a list of no less than twenty-five (25) proposed arbitrators (fifteen (15) if a single arbitrator is to be selected) having the credentials referenced above. Within twenty-five (25) days of receiving such list, the Parties shall rank at least sixty-five percent (65%) of the proposed arbitrators on the initial CPR list, after exercising cause challenges. The Parties may then interview the five (5) candidates (three (3) if a single arbitrator is to be selected) with the highest combined rankings for no more than one (1) hour each and, following the interviews, may exercise one (1) peremptory challenge each. The panel will consist of the remaining three (3) candidates (or one, if one arbitrator is to be selected) with the highest combined rankings. In the event these procedures fail to result in selection of the required number of arbitrators, CPR shall select the appropriate number of arbitrators from among the members of the various CPR Panels of Distinguished Neutrals, allowing each side challenges for cause and three (3) peremptory challenges each.

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(e) In the event the Parties cannot agree upon procedures for discovery and conduct of the hearing meeting the schedule set forth in paragraph (c) above, then the arbitrator(s) shall set dates for the hearing, any post-hearing briefing, and the issuance of the award in accord with the paragraph (c) schedule. The arbitrator(s) shall provide for discovery according to those time limits, giving recognition to the understanding of the Parties that they contemplate reasonable discovery, including document demands and depositions, but that such discovery be limited so that the paragraph (c) schedule may be met without difficulty. In no event will the arbitrator(s), absent agreement of the Parties, allow more than a total of ten (10) days for the hearing or permit either side to obtain more than a total of forty (40) hours of deposition testimony from all witnesses, including both fact and expert witnesses, or serve more than twenty (20) individual requests for documents, including subparts, or twenty (20) individual requests for admission or interrogatories, including subparts. Multiple hearing days will be scheduled consecutively to the greatest extent possible.

(f) The arbitrator(s) must render their award by application of the substantive law of California and are not free to apply "amiable compositeur" or "natural justice and equity." The arbitrator(s) shall render a written opinion setting forth findings of fact and conclusions of law with the reasons therefore stated. A transcript of the evidence adduced at the hearing shall be made and shall, upon request, be made available to either Party. The arbitrator(s) shall have power to exclude evidence on grounds of hearsay, prejudice beyond its probative value, redundancy, or irrelevance and no award shall be overturned by reason of such ruling on evidence. To the extent possible, the arbitration hearings and award will be maintained in confidence.

(g) In the event the panel's award exceeds $5 million in monetary damages or includes or consists of equitable relief, or rejects a claim in excess of that amount or for that relief, then the losing Party may obtain review of the arbitrators' award or decision by a single appellate arbitrator (the "**Appeal Arbitrator**") selected from the CPR Panels of Distinguished Neutrals by agreement or, failing agreement within seven (7) working days, pursuant to the selection procedures specified in paragraph (d) above. If CPR cannot provide such services, the Parties will together select another provider of arbitration services that can. No Appeal Arbitrator shall be selected unless he or she can commit to rendering a decision within forty-five (45) days following oral argument as provided in paragraph (h). Any such review must be initiated within thirty (30) days following the rendering of the award referenced in (f) above.

(h) The Appeal Arbitrator will make the same review of the arbitration panel's ruling and its bases that the U.S. Court of Appeals of the Circuit where the arbitration hearings are held would make of findings of fact and conclusions of law rendered by a district court after a bench trial and then modify, vacate or affirm the arbitration panel's award or decision accordingly, or remand to the panel for further proceedings. The Appeal Arbitrator will consider only the arbitration panel's findings of fact and conclusions of law, pertinent portions of the hearing transcript and evidentiary record as submitted by the Parties, opening and reply briefs of

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the Party pursuing the review, and the answering brief of the opposing Party, plus a total of no more than four (4) hours of oral argument evenly divided between the Parties. The Party seeking review must submit its opening brief and any reply brief within seventy-five (75) and one hundred thirty (130) days, respectively, following the date of the award under review, whereas the opposing Party must submit its responsive brief within one hundred ten (110) days of that date. Oral argument shall take place within five (5) months after the date of the award under review, and the Appeal Arbitrator shall render a decision within forty-five (45) days following oral argument. That decision will be final and not subject to further review, except pursuant to the Federal Arbitration Act.

(i) The Parties consent to the jurisdiction of the Federal District Court for the district in which the arbitration is held for the enforcement of these provisions and the entry of judgment on any award rendered hereunder (including after review by the Appeal Arbitrator where such an appeal is pursued). Should such court for any reason lack jurisdiction, any court with jurisdiction shall act in the same fashion.

(j) Each Party has the right before or, if the arbitrator(s) cannot hear the matter within an acceptable period, during the arbitration to seek and obtain from the appropriate court provisional remedies such as attachment, preliminary injunction, replevin, etc. to avoid irreparable harm, maintain the *status quo*, or preserve the subject matter of the arbitration.

(k) EACH PARTY HERETO WAIVES ITS RIGHT TO TRIAL BY JURY OF ANY ISSUE RELATED TO THIS AGREEMENT.

(l) EACH PARTY HERETO WAIVES ANY CLAIM TO PUNITIVE, EXEMPLARY OR MULTIPLIED DAMAGES FROM THE OTHER RESULTING FROM THIS AGREEMENT.

(m) EACH PARTY HERETO WAIVES ANY CLAIM OF CONSEQUENTIAL DAMAGES FROM THE OTHER RELATED TO THIS AGREEMENT.

(n) NOTWITHSTANDING THE FOREGOING, NOTHING HEREIN IS INTENDED TO OR SHALL LIMIT THE INDEMNIFICATION OBLIGATION OF A PARTY PROVIDED FOR UNDER ARTICLE 8.

10.12 Tolling of Time Periods. In the event that a controversy or claim has been raised and is in the process of dispute resolution in accordance with Sections 10.9, 10.10 or 10.11, any applicable time period governing the underlying controversy or claim shall be tolled pending the outcome of the resolution process after which the time period shall again begin to run.

10.13 Notices and Deliveries. Any notice, request, delivery, approval or consent required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given if delivered in person, transmitted by telecopier (receipt verified) or by express courier service (signature required) or five (5) days after it was sent by registered

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letter, return receipt requested (or its equivalent), to the Party to which it is directed at its address or facsimile number shown below or such other address or facsimile number as such Party shall have last given by notice to the other Parties.

If to Janssen, addressed to:

Janssen Pharmaceutica NV
30 Turnhoutseweg
2340 Beerse, Belgium
Attention of: Managing Director
Fax: +32 14 60 8296

With copy to:

Johnson & Johnson Law Department Europe
6 Lenneke Marelaan
1932 St. Stevens Woluwe, Belgium
Attention of: Head of the Law Department Europe
Fax: +32 2 749 2558

If to Metabolex, addressed to:

Metabolex, Inc.
3876 Bay Center Place
Hayward, CA 94545
Attention of: General Counsel
Fax: (510) 293-6853

10.14 Waiver. A waiver by either Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any subsequent breach hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be in limitation of any other remedy, right, undertaking, obligation or agreement of either Party.

10.15 Translation. This Agreement is in English language only, which language shall be controlling in all respects, and all versions hereof in any other language shall be for accommodation only and shall not be binding upon the Parties. All communications and notices to be made or given pursuant to this Agreement, and any dispute proceeding related to or arising hereunder, shall be in the English language. If there is a discrepancy between any translation of this Agreement and this Agreement, this Agreement shall prevail.

10.16 Export Laws. Notwithstanding anything to the contrary contained herein, all obligations of Metabolex and Janssen are subject to prior compliance with U.S. export regulations and such other U.S. laws and regulations as may be applicable, and to obtaining all necessary approvals required by the applicable agencies of the government of the U.S. or the

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European Union. Metabolex and Janssen, respectively, shall each use its reasonable efforts to obtain such approvals for its own activities. Each Party shall cooperate with the other Party and shall provide assistance to the other Party as reasonably necessary to obtain any required approvals.

10.17 Severability. When possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be prohibited by or invalid under applicable law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement. The Parties shall make a good faith effort to replace the invalid or unenforceable provision with a valid one that conforms as nearly as possible with the original intent of the Parties.

10.18 No Implied Licenses. Except as expressly and specifically provided under this Agreement, the Parties agree that neither Party is granted any implied rights to or under any of the other Party's current or future patents, trade secrets, copyrights, moral rights, trade or service marks, trade dress, or any other intellectual property rights.

10.19 Third Party Beneficiaries. Except for the rights of the Metabolex Indemnitees and Janssen Indemnitees set forth in Article 8, all rights, benefits and remedies under this Agreement are solely intended for the benefit of Metabolex and Janssen, and no Third Party shall have any rights whatsoever to (i) enforce any obligation contained in this Agreement; (ii) seek a benefit or remedy for any breach of this Agreement; or (iii) take any other action relating to this Agreement under any legal theory, including but not limited to, actions in contract, tort (including but not limited to negligence, gross negligence and strict liability), or as a defense, setoff or counterclaim to any action or claim brought or made by the Parties.

10.20 Advice of Counsel. Metabolex and Janssen have each consulted counsel of their choice regarding this Agreement, and each acknowledges and agrees that this Agreement shall not be deemed to have been drafted by one Party or another and will be construed accordingly.

10.21 Other Obligations. Except as expressly provided in this Agreement or as separately agreed upon in writing between Metabolex and Janssen, each Party shall bear its own costs incurred in connection with the implementation of the obligations under this Agreement.

10.22 Governmental Matters.

(a) To the extent, if any, that a Party concludes in good faith that it is required to file or register this Agreement or a notification thereof with any governmental authority, including without limitation the U.S. Securities and Exchange Commission, the U.S. Department of Justice, the U.S. Federal Trade Commission and the Competition Directorate of the Commission of the European Communities, in accordance with applicable laws and regulations, such Party may do so, and the other Party shall cooperate in such filing or notification and shall execute all documents reasonably required in connection therewith, at the expense of the requesting Party. The Parties shall promptly notify each other as to the activities or inquires of any such governmental authority relating to this Agreement, and shall cooperate, to respond to any request for further information therefrom at the expense of the requesting Party.

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(b) Metabolex may, at its expense, register the exclusive license granted under this Agreement in any country or community or association of countries. Janssen shall reasonably cooperate in such registration at Metabolex's expense. Upon request by Metabolex, Janssen agrees promptly to execute any "short form" licenses developed in a form reasonably acceptable to both Metabolex and Janssen and reasonably submitted to it by Metabolex from time to time in order to effect the foregoing registration in such country. No such "short form" license shall be deemed to amend or be used to interpret this Agreement. If there is any conflict between such a license or other recordation document and this Agreement, this Agreement shall control.

10.23 Counterparts. This Agreement may be executed simultaneously in any number of counterparts, any one of which need not contain the signature of more than one Party but all such counterparts taken together shall constitute one and the same agreement.

[The remainder of this page has been intentionally left blank]

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IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized officers as of the day and year first above written.

JANSSEN PHARMACEUTICA NV

By: /s/ Didier De Chaffoy De Courcelles
Name: Didier De Chaffoy De Courcelles
Title: Board member

By: /s/ René Hex
Name: René Hex
Title: Board member

METABOLEX, INC.

By: /s/ Harold Van Wart
Name: Harold Van Wart
Title: Chief Executive Officer

Exhibit A:	Weighted Average Percentage Discount
Exhibit B:	Description of Numbered PPAR-δ Compounds
Exhibit C:	PPAR-δ Patents
Exhibit D:	Materials to be Transferred
Exhibit E:	Description of [*]
Exhibit F:	Replacement Compound Patents

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EXHIBIT A

WEIGHTED AVERAGE PERCENTAGE DISCOUNT

(see attached)

[*]

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EXHIBIT B

DESCRIPTION OF NUMBERED PPAR-δ COMPOUNDS

[*]

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EXHIBIT C

PPAR-δ PATENTS

[*]

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EXHIBIT D

MATERIALS TO BE TRANSFERRED

[*]

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EXHIBIT E

DESCRIPTION OF [*]

[*]

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EXHIBIT F

REPLACEMENT COMPOUND PATENTS

[*]

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Exhibit 31.1

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)) 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) 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

   c) 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 14, 2014

/s/ Harold Van Wart
Harold Van Wart
Chief Executive Officer

Exhibit 31.2

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)) 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) 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

   c) 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 14, 2014

/s/ Sujal Shah
Sujal Shah
Chief Financial Officer

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), 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 period ended September 30, 2014, 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 14, 2014.

/s/ Harold Van Wart	/s/ Sujal Shah
Harold Van Wart	Sujal Shah
Chief Executive Officer	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.