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, 2022

OR

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

FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission File Number 001-36500

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

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

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, anon-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

As of October 31, 2022, there were 84,681,063 shares of the registrant's common stock outstanding.

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

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 30,691	$ 125,806
Marketable securities	122,724	60,729
Prepaid research and development expenses	668	2,371
Other prepaid expenses and current assets	1,041	2,193
Total current assets	155,124	191,099
Property and equipment, net	845	1,178
Non-current marketable securities	—	8,067
Operating lease right-of-use asset	197	254
Other assets	3,081	1,720
Total assets	$ 159,247	$ 202,318
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 479	$ 2,728
Accrued research and development expenses	6,622	9,752
Other accrued liabilities	5,610	5,886
Total current liabilities	12,711	18,366
Development financing liability	86,152	50,320
Long-term portion of operating lease liability	206	695
Total liabilities	99,069	69,381
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value: 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.0001 par value: 200,000,000 shares authorized; 84,681,063 and 84,677,939 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	8	8
Additional paid-in capital	906,968	899,798
Accumulated other comprehensive loss	(574)	(13)
Accumulated deficit	(846,224)	(766,856)
Total stockholders' equity	60,178	132,937
Total liabilities and stockholders' equity	$ 159,247	$ 202,318

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 15,459	$ 17,010	$ 51,765	$ 46,137
General and administrative	5,904	5,179	17,869	16,936
Total operating expenses	21,363	22,189	69,634	63,073
Loss from operations	(21,363)	(22,189)	(69,634)	(63,073)
Other income (expense), net:				
Interest income	677	29	1,098	140
Interest expense	(3,819)	(522)	(10,832)	(522)
Total other income (expense), net	(3,142)	(493)	(9,734)	(382)
Net loss	$ (24,505)	$ (22,682)	$ (79,368)	$ (63,455)
Other comprehensive loss:				
Unrealized loss on marketable securities	(133)	(2)	(561)	(9)
Total other comprehensive loss	(133)	(2)	(561)	(9)
Comprehensive loss	$ (24,638)	$ (22,684)	$ (79,929)	$ (63,464)
Basic and diluted net loss per common share	$ (0.28)	$ (0.33)	$ (0.90)	$ (0.92)
Weighted average common shares outstanding used to calculate basic and diluted net loss per common share	87,804,272	69,022,937	87,803,388	68,985,112

See accompanying notes to the condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2022	2021
Operating activities		
Net loss	$ (79,368)	$ (63,455)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	525	515
Stock-based compensation expense	7,156	7,611
Write-off of deferred financing costs	—	312
Accretion of development financing liability	10,832	522
Net accretion and amortization of investments in marketable securities	(283)	543
Changes in assets and liabilities:		
Other prepaid expenses and current assets	2,855	(725)
Other assets	(1,413)	(1,514)
Accounts payable	(2,061)	512
Accrued research and development expenses	(3,130)	1,660
Other accrued liabilities	(437)	(1,169)
Net cash used in operating activities	(65,324)	(55,188)
Investing activities		
Purchases of property and equipment	(135)	(87)
Purchases of marketable securities	(162,346)	(44,607)
Proceeds from maturities of marketable securities	108,140	117,360
Net cash (used in) provided by investing activities	(54,341)	72,666
Financing activities		
Proceeds from issuance of common stock pursuant to equity award plans	9	205
Proceeds from development financing, net of transaction costs	25,000	23,087
Issuance costs paid for issuance of common stock	(459)	—
Net cash provided by financing activities	24,550	23,292
Net (decrease) increase in cash and cash equivalents	(95,115)	40,770
Cash and cash equivalents at beginning of period	125,806	28,193
Cash and cash equivalents at end of period	$ 30,691	$ 68,963
Supplemental disclosure		
Cash paid for amounts included in the measurement of lease liabilities	$ 513	$ 498
Supplemental non-cash investing and financing activities		
Accrued financing costs	$ —	$ 350
Accrued costs for other assets	$ 52	$ —

See accompanying notes to the condensed consolidated financial statements.

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

	Three and Nine Months Ended September 30, 2022					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances as of December 31, 2021	84,677,939	$ 8	$899,798	$ (13)	$ (766,856)	$ 132,937
Issuance costs related to issuance of common stock and pre-funded warrants	—	—	5	—	—	5
Stock-based compensation expense	—	—	2,414	—	—	2,414
Net loss	—	—	—	—	(27,769)	(27,769)
Net unrealized loss on marketable securities	—	—	—	(206)	—	(206)
Balances as of March 31, 2022	84,677,939	$ 8	$902,217	$ (219)	$ (794,625)	$ 107,381
Stock-based compensation expense	—	—	2,392	—	—	2,392
Net loss	—	—	—	—	(27,094)	(27,094)
Net unrealized loss on marketable securities	—	—	—	(222)	—	(222)
Balances as of June 30, 2022	84,677,939	$ 8	$904,609	$ (441)	$ (821,719)	$ 82,457
Issuance of common stock upon exercise of stock options	3,124	—	9	—	—	9
Stock-based compensation expense	—	—	2,350	—	—	2,350
Net loss	—	—	—	—	(24,505)	(24,505)
Net unrealized loss on marketable securities	—	—	—	(133)	—	(133)
Balances as of September 30, 2022	84,681,063	$ 8	$906,968	$ (574)	$ (846,224)	$ 60,178

	Three and Nine Months Ended September 30, 2021					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances as of December 31, 2020	68,946,092	$ 7	$ 819,549	$ 8	$ (676,858)	$ 142,706
Stock-based compensation expense	—	—	2,505	—	—	2,505
Net loss	—	—	—	—	(17,551)	(17,551)
Net unrealized loss on marketable securities	—	—	—	(14)	—	(14)
Balances as of March 31, 2021	68,946,092	$ 7	$ 822,054	$ (6)	$ (694,409)	$ 127,646
Issuance of common stock upon exercise of stock options	51,846	—	106	—	—	106
Stock-based compensation expense	—	—	2,557	—	—	2,557
Net loss	—	—	—	—	(23,222)	(23,222)
Net unrealized gain on marketable securities	—	—	—	7	—	7
Balances as of June 30, 2021	68,997,938	$ 7	$ 824,717	$ 1	$ (717,631)	$ 107,094
Issuance of common stock upon exercise of stock options	46,031	—	99	—	—	99
Stock-based compensation expense	—	—	2,549	—	—	2,549
Net loss	—	—	—	—	(22,682)	(22,682)
Net unrealized loss on marketable securities	—	—	—	(2)	—	(2)
Balances as of September 30, 2021	69,043,969	$ 7	$ 827,365	$ (1)	$ (740,313)	$ 87,058

See accompanying notes to the condensed consolidated financial statements.

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

1. Organization and Description of Business

CymaBay Therapeutics, Inc. (the Company or CymaBay) is a clinical-stage biopharmaceutical company focused on developing and providing access to innovative therapies for patients with liver and other chronic diseases with high unmet medical need. The Company's key clinical development candidate is seladelpar. Seladelpar has been under development primarily for the treatment of primary biliary cholangitis (PBC), a rare liver disease. The Company was incorporated in Delaware in October 1988 as Transtech Corporation. The Company's headquarters and operations are located in Newark, California and it operates in one segment.

Liquidity

The Company has incurred net operating losses and negative cash flows from operations since its inception. During the three and nine months ended September 30, 2022, the Company incurred a net loss of $24.5 million and $79.4 million, respectively, and during the nine months ended September 30, 2022, used $65.3 million of cash in operations. At September 30, 2022, the Company had an accumulated deficit of $846.2 million.

Historically, the Company has incurred substantial research and development expenses in the course of studying its product candidates in clinical trials. To date, none of the Company's product candidates have been approved for marketing and sale, and the Company has not recorded any revenue from product sales. Generally, the Company's ability to achieve profitability is dependent on its ability to successfully develop, acquire or in-license additional product candidates, conduct clinical trials for those product candidates, obtain regulatory approvals, and support commercialization activities for those product candidates. Any products developed will require approval of the U.S. Food and Drug Administration (FDA) or a foreign regulatory authority prior to commercial sale. The regulatory approval process is expensive, time-consuming, and uncertain, and any denial or delay of approval could have a material adverse effect on the Company. Even if approved, the Company's products may not achieve market acceptance and will face competition from both generic and branded pharmaceutical products.

As of September 30, 2022, the Company had cash, cash equivalents and marketable securities totaling $153.4 million, which the Company believes is sufficient to fund its current operating plan for at least twelve months from the issuance date of its financial statements. The Company has historically obtained, and expects to obtain in the future, additional financing to fund its business strategy through: future equity offerings; debt financing; one or more possible licenses, collaborations or other similar arrangements with respect to development and/or commercialization rights of the Company's product candidates; or a combination of the above. It is unclear if or when any such transactions will occur, on satisfactory terms or at all. The Company's failure to raise capital as and when needed could have a negative impact on its financial condition and its ability to pursue its business strategies. If adequate funds are not available to the Company, it could have a material adverse effect on the Company's business, results of operations, and financial condition. Market volatility, whether resulting from the global novel coronavirus disease (COVID-19) pandemic, geopolitics or other factors could also adversely impact the Company's ability to access capital when and as needed. Failure to raise sufficient capital when needed could require the Company to significantly delay, scale back or discontinue one or more of its product development programs or commercialization efforts, or other aspects of its business plans, and the Company's operating results and financial condition would be adversely affected.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying interim condensed consolidated financial statements are unaudited and are comprised of the accounts of CymaBay and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. The Company has no unconsolidated subsidiaries or investments accounted for under the equity method.

These unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP), which requires management to make informed estimates and assumptions that impact the amounts and disclosures reported in the condensed consolidated financial statements and accompanying notes, and the requirements of the United States Securities and Exchange Commission (SEC) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted.

In management's opinion, the unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited financial statements and include normal recurring adjustments necessary for the fair presentation of the Company's financial position and its results of operations and comprehensive loss and its cash flows for the periods presented. These statements do not include all disclosures required by U.S. GAAP and should be read in conjunction with the Company's financial statements and accompanying notes for the fiscal year ended December 31, 2021, which is contained in the Company's Annual Report on Form 10-K as filed with the SEC on March 17, 2022. The results for the three and nine months ended September 30, 2022 are not necessarily indicative of results to be expected for the entire year ending December 31, 2022 or future operating periods.

The condensed consolidated financial statements have been prepared in accordance with U.S. GAAP, which requires management to make estimates and assumptions that affect the amounts and disclosures reported in the condensed consolidated financial statements and accompanying notes. Management bases its estimates on historical experience and on assumptions believed to be reasonable under the circumstances. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes, and management must select an amount that falls within that range of reasonable estimates. Actual results could differ materially from those estimates and assumptions. These estimates form the basis for making judgments about the carrying values of assets and liabilities when these values are not readily apparent from other sources. Estimates are assessed each reporting period and updated to reflect current information and any changes in estimates will generally be reflected in the period first identified.

Fair Value of Financial Instruments

The Company's financial instruments during the periods reported consist of cash, cash equivalents, marketable securities, accounts payable, certain accrued liabilities, and the development financing liability.

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 minimizes the use of unobservable inputs and is as follows:

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

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

Level 3—Inputs that are significant to the fair value measurement and are unobservable (i.e. supported by little or no market activity), which requires the reporting entity to develop its own valuation techniques and assumptions.

The carrying amounts of cash, accounts payable, and certain accrued liabilities approximate their related fair values due to the short-term nature of these instruments. Cash is classified as level 1 and accounts payable and accrued liabilities as level 2 under the fair value hierarchy.

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

	As of September 30, 2022			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$24,208	$ —	$ —	$ 24,208
Total cash equivalents	24,208	—	—	24,208
Marketable securities:				
U.S. and foreign commercial paper	—	58,720	—	58,720
U.S. and foreign corporate debt securities	—	24,681	—	24,681
Supranational debt securities	—	12,814	—	12,814
U.S. agency securities	—	2,950	—	2,950
U.S. treasury securities	—	23,559	—	23,559
Total marketable securities	—	122,724	—	122,724
Total assets measured at fair value	$24,208	$122,724	$ —	$146,932

	As of December 31, 2021			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$85,638	$ —	$ —	$ 85,638
Total cash equivalents	85,638	—	—	85,638
Marketable securities:				
U.S. and foreign commercial paper	—	28,760	—	28,760
U.S. and foreign corporate debt securities	—	23,535	—	23,535
Asset-backed securities	—	8,522	—	8,522
U.S. treasury securities	—	7,979	—	7,979
Total marketable securities	—	68,796	—	68,796
Total assets measured at fair value	$85,638	$68,796	$ —	$154,434

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

The fair value of the Company's development financing liability is $71.8 million. The development financing liability is classified as level 3 under the fair value hierarchy, as its valuation is based on a discounted cash flow model that uses unobservable inputs such as the discount rate, estimated timing of regulatory approval and attainment of certain sales milestones.

Cash, Cash Equivalents, and Marketable Securities

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

The Company invests excess cash in marketable securities with high credit ratings. These securities consist primarily of corporate debt, commercial paper, asset-backed securities, U.S. treasury securities, and supranational debt securities and are classified as "available-for-sale." The Company considers marketable securities as short-term investments if the maturity date is less than or equal to one year from the balance sheet date. The Company considers marketable securities as long-term investments if the maturity date is in excess of one year from the balance sheet date.

Realized gains and losses from the sale of marketable securities, if any, are calculated using the specific-identification method. Realized gains and losses and declines in value judged to be other-than-temporary are included in interest income or expense in the condensed consolidated statements of operations and comprehensive loss. Unrealized holding gains and losses are reported in accumulated other comprehensive loss in the condensed consolidated balance sheets. To date, the Company has not recorded any impairment charges on its marketable securities related to other-than-temporary declines in market value. In determining whether a decline in market value is other-than-temporary, various factors are considered, including the cause, duration of time and severity of the impairment, any adverse changes in the investees' financial condition, and the Company's intent and ability to hold the security for a period of time sufficient to allow for an anticipated recovery in market value.

Unrealized gains and losses of the Company's available-for-sale marketable securities as of September 30, 2022 and December 31, 2021 are presented in the tables below (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
As of September 30, 2022:				
Cash equivalents:				
Money market funds	$ 24,208	$ —	$ —	$ 24,208
Total cash equivalents	24,208	—	—	24,208
Current marketable securities:				
U.S. and foreign commercial paper	58,720	—	—	58,720
U.S. and foreign corporate debt securities	24,996	—	(315)	24,681
Supranational debt securities	12,904	—	(90)	12,814
US. agency securities	3,000	—	(50)	2,950
U.S. treasury securities	23,678	—	(119)	23,559
Total current marketable securities	123,298	—	(574)	122,724
Total marketable securities	$147,506	$ —	$ (574)	$146,932

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
As of December 31, 2021:				
Cash equivalents:				
Money market funds	$ 85,638	$ —	$ —	$ 85,638
Total cash equivalents	85,638	—	—	85,638
Current marketable securities:				
U.S. and foreign commercial paper	28,760	—	—	28,760
U.S. and foreign corporate debt securities	15,476	—	(8)	15,468
Asset-backed securities	8,524	—	(2)	8,522
U.S. treasury securities	7,982	—	(3)	7,979
Total current marketable securities	60,742	—	(13)	60,729
Non-current marketable securities:				
U.S. corporate debt securities	8,067	2	(2)	8,067
Total marketable securities	$154,447	$ 2	$ (15)	$154,434

The following table shows the fair value of the Company's marketable securities, by contractual maturity, as of September 30, 2022 (in thousands):

Due less than 1 year	$122,724
Due between 1 and 2 years	—
Total fair value	$122,724

Concentration of Risk

Cash, cash equivalents, and marketable securities consist of financial instruments that potentially subject the Company to a concentration of credit risk to the extent of the fair value recorded on the balance sheet. The Company invests cash that is not required for immediate operating needs primarily in highly liquid instruments that bear minimal risk. The Company has established guidelines relating to the quality, diversification, and maturities of securities to enable the Company to manage its credit risk. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash, cash equivalents and investments and issuers of investments to the extent recorded on the condensed consolidated balance sheets.

Certain materials and key components that the Company utilizes in its operations are obtained through single suppliers. Since the suppliers of key components and materials must be named in a new drug application NDA filed with the FDA for a product, significant delays can occur if the qualification of a new supplier is required. If delivery of material from the Company's suppliers were interrupted for any reason, the Company may be unable to supply any of its product candidates for clinical trials.

Other Risks and Uncertainties

In March 2020, the World Health Organization declared the global novel coronavirus disease(COVID-19) outbreak a pandemic. To date, the Company's operations have not been significantly impacted by the COVID-19 outbreak. However, the Company continues to monitor potential risks and uncertainties associated with operating its business during the pandemic. These risks include, but are not limited to, government advisories and restrictions on travel and workplace access, workforce shortages, and global supply chain delays, all of which could potentially impact the Company's ability to conduct its critical drug development and regulatory compliance activities. The Company cannot predict the specific extent, duration, or full impact that the COVID-19 outbreak will have on its consolidated financial condition and operations. The impact of theCOVID-19 coronavirus outbreak on the financial performance of the Company will depend on future developments, including the duration and spread of the outbreak and related governmental advisories and restrictions. These developments and the impact of COVID-19 on the financial markets and the overall economy are highly uncertain. If the financial markets and/or the overall economy are impacted for an extended period, the Company's results may be adversely affected.

Research and Development Expenses

Research and development expenses consist of costs incurred in identifying, developing, and testing product candidates. These expenses consist primarily of costs for research and development personnel, including related stock-based compensation; contract research organizations (CRO) and other third parties that assist in managing, monitoring, and analyzing clinical trials; investigator and site fees; laboratory services; consultants; contract manufacturing services; non-clinical studies, including materials; and allocated expenses, such as depreciation of assets, and facilities and information technology that support research and development activities. Research and development costs are expensed as incurred, including expenses that may or may not be reimbursed under research and development funding arrangements. Payments made prior to the receipt of goods or services to be used in research and development are recorded as prepaid assets until the goods are received or services are rendered. Such payments are evaluated for current or long-term classification based on when they will be realized. Additionally, if expectations change such that the Company does not expect goods to be delivered or services to be rendered, such prepayments are charged to expense.

The Company records expenses related to clinical studies and manufacturing development activities based on its estimates of the services received and efforts expended pursuant to contracts with multiple CROs and manufacturing vendors that conduct and manage these activities on its behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows. There may be instances in which payments made to the Company's vendors will exceed the level of services provided and result in a prepayment. Payments under some of these contracts depend on factors such as the successful enrollment of subjects and the completion of clinical trial milestones. In amortizing or accruing service fees, the Company estimates the time period over which services will be performed, enrollment of subjects, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the Company's estimate, the Company will adjust the accrued or prepaid expense balance accordingly. To date, there have been no material differences from the Company's estimates to the amounts actually incurred.

Development Financing Agreement

The Company accounts for the Financing Agreement (see Note 4) as a debt instrument. Accordingly, the Company has recorded payments received under the Financing Agreement as part of a development financing liability in the Company's condensed consolidated balance sheet. The liability is recorded at amortized cost and accreted to the contractual success fee amounts based on the estimated timing of regulatory approval and attainment of certain sales milestones using an imputed interest rate. Certain transaction fees incurred specifically to complete the Financing Agreement were capitalized and recorded as a reduction to the carrying amount of the development financing liability and are being amortized to interest expense using the effective interest rate method.

There are several factors that could affect the estimated timing of regulatory approval and attainment of sales milestones, some of which are not entirely within the Company's control. Therefore, at each reporting date, the Company reassesses the estimated timing of regulatory approval and attainment of sales milestones and the expected contractual success fee payments due therefrom. If the timing and/or amount of such expected payments is materially different than original estimates, the Company will prospectively adjust the accretion of the development financing liability and the imputed interest rate.

The Company identified certain contingent repayment features in the Financing Agreement that are required to be bifurcated from the debt host instrument as embedded derivative liabilities; however, the Company determined the fair value of these features, both individually and in the aggregate, was immaterial at inception and as of September 30, 2022. The fair value of these features will be assessed at each reporting date and will be marked to market, if material. To determine the amount to record for the embedded derivative liabilities, the Company must assess the probability of occurrence of various potential future events that could affect the timing and/or amount of future cash flows related to the Financing Agreement.

Stock-Based Compensation

Stock-based compensation is measured at fair value on the grant date of the award. Compensation cost is recognized as expense on a straight-line basis over the vesting period for options with service conditions, and forfeitures are accounted for as they occur. The Company uses the Black-Scholes option pricing model to determine the fair value of stock option awards. The determination of fair value for stock-based awards using an option-pricing model requires management to make certain assumptions regarding subjective input variables such as expected term, dividends, volatility and risk-free rate. If actual results are not consistent with the Company's assumptions and judgments used in making these estimates, the Company may be required to increase or decrease compensation expense, which could be material to the Company's results of operations.

Recently Issued Accounting Pronouncements

ASU 2020-06

In August 2020, the FASB issued ASU 2020-06, Debt—*Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which amends the guidance for accounting for certain financial instruments with characteristics of liabilities and equity. The new guidance simplifies aspects of the accounting for convertible debt instruments and convertible preferred stock by limiting the number of accounting models, which results in fewer embedded conversion features being separately recognized from the host contract as compared with previous GAAP. The guidance is effective for the Company beginning January 1, 2024, and early adoption is permitted. The Company is currently assessing the impact of this standard on its condensed consolidated financial statements and related disclosures.

ASU 2016-13

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326): *Measurement of Credit Losses on Financial Instruments*, an amendment which modifies the measurement and recognition of credit losses for most financial

assets and certain other instruments. The amendment updates the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the "incurred loss" model with an "expected loss" model. Accordingly, these financial assets will be presented at the net amount expected to be collected. The amendment also requires that credit losses related to available-for-sale debt securities be recorded as an allowance through net income rather than reducing the carrying amount under the current, other-than-temporary-impairment model. In November 2019, FASB issued ASU No. 2019-10, Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815) and Leases (Topic 842), which deferred the adoption deadline for smaller reporting companies to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted, and entities are required to use a modified retrospective approach, with certain exceptions. The Company is currently assessing this standard and does not anticipate a material impact to its condensed consolidated financial statements and related disclosures.

3. Other Accrued Liabilities

Other accrued liabilities consist of (in thousands):

	September 30, 2022	December 31, 2021
Accrued compensation	$ 4,022	$ 3,986
Accrued professional fees and other	949	1,333
Current portion of operating lease liability	639	567
Total other accrued liabilities	$ 5,610	$ 5,886

4. Development Financing Agreement

On July 30, 2021 (the Effective Date), the Company entered into a Development Financing Agreement (the Financing Agreement) withan affiliate of Abingworth LLP (Abingworth) to provide funding to the Company to support its development of seladelpar for the treatment of primary biliary cholangitis (PBC). The Financing Agreement provides the Company up to $100.0 million in funding, of which $25.0 million was provided in August 2021, $25.0 million was provided in November 2021, and $25.0 million was provided in January 2022. The use of proceeds from the funding is limited to PBC "Development Program" costs incurred or paid as defined in the Financing Agreement. In return, the Company will pay to Abingworth:

(1) contingent upon the first to occur of regulatory approval of seladelpar for the treatment of PBC in the U.S., U.K., Germany, Spain, Italy or France (Regulatory Approval), fixed success payments equal to 2.0x of the funding provided, consisting of $10 million payable within 90 days after the Regulatory Approval and thereafter, payments due on the first six anniversaries of the Regulatory Approval in the amounts of $15.0 million, $22.5 million, $22.5 million, $25.0 million, $27.5 million and $27.5 million, respectively and

(2) variable success payments equal to 1.1x of the funding provided, consisting of sales milestone payments of (x) $17.5 million and $27.5 million, respectively upon first reaching certain cumulative U.S. product sales thresholds, and (y) $37.5 million upon first reaching a specified U.S. product sales run rate.

Promptly following receipt of Regulatory Approval, the Company is required to execute a note agreement and deliver a promissory note to Abingworth within two business days to convert the fixed and variable success payments into a note payable. At the time that Abingworth receives, collectively, an aggregate of 3.1x of the funding provided (approximately $232.5 million), the Company's payment obligations under the Financing Agreement will be fully satisfied. The Company has the option to satisfy its payment obligations to Abingworth upon Regulatory Approval, or a change of control of the Company, by paying an amount equal to the remaining payments payable to Abingworth subject to a mid-single-digit discount rate. Upon a change of control of the Company, an acceleration payment of 1.35x of the funding provided is payable, net of payments already made to Abingworth and creditable against future payments to Abingworth.

Pursuant to the Financing Agreement, the Company granted Abingworth a security interest in all its assets (other than intellectual property not related to seladelpar), provided that the Company is permitted to incur certain indebtedness. The security interest will terminate when the Company has paid Abingworth 2.0x of the funding provided or upon certain terminations of the Financing Agreement.

The Company had an option to receive an additional $25 million (the Optional Funding) within approximately two months of enrollment completion of the Company's Phase 3 RESPONSE clinical trial. The Company did not exercise the Optional Funding and the option has expired.

The Financing Agreement provides for negative, affirmative and additional covenants, which the Company must comply with for the duration of the Financing Agreement term. As of September 30, 2022, the Company was in compliance with all covenants stipulated in the Financing Agreement.

In certain instances, upon the termination of the Financing Agreement, the Company will be obligated to pay Abingworth a multiple of the amounts paid to the Company under the Financing Agreement, including specifically:

(i) 310% of such amounts in the event that Abingworth terminates the Financing Agreement due to (x) a Fundamental Breach, as defined in the Financing Agreement, (y) the bankruptcy of the Company, or (z) a safety concern resulting from gross negligence on the part of the Company or due to a safety concern that was material on the Effective Date and the material data showing such safety concern was not publicly known, disclosed to Abingworth, or in the diligence room made available to Abingworth,

(ii) 200% of such amounts in the event the Financing Agreement is terminated due to (x) Material Breach, as defined in the Financing Agreement, by the Company or (y) the security interests of Abingworth being invalidated or terminated other than as set forth in the Financing Agreement, and

(iii) 100% of such amounts in the event of certain irresolvable disagreements within the executive review committee overseeing the Company's development of seladelpar.

In addition, if, following certain terminations, the Company continues to develop seladelpar for the treatment of PBC and obtains regulatory approval, it will make the payments to Abingworth as if the Financing Agreement had not been terminated, less any payments made upon termination.

The Company shall not be obligated to make any payments to Abingworth under certain instances of technical or regulatory failure of the PBC development program as defined in the Financing Agreement.

As part of the arrangement, an executive review committee was established between the Company and Abingworth to discuss the Company's development of seladelpar.

The Company evaluated the Financing Agreement and determined it to be a research and development funding arrangement with the characteristics of a debt instrument, as the transfer of financial risk to Abingworth was not considered substantive and genuine. Accordingly, the Company has recorded payments received under the Financing Agreement as part of a development financing liability in its condensed consolidated balance sheets. The Company accounts for the overall development financing liability at amortized cost based on the estimated timing of regulatory approval and attainment of certain sales milestones and the contractual success fee payments expected to be due therefrom, as discounted using an imputed interest rate. The development financing liability will be accreted as interest expense to its expected future repayment amount over the expected life of the agreement using the effective interest rate method. Certain legal and financial advisory fees incurred specifically to complete the Financing Agreement were capitalized and recorded as a reduction to the carrying amount of the development financing liability and will also be amortized to interest expense using the effective interest method.

There are several factors that could affect the estimated timing of regulatory approval and attainment of sales milestones, some of which are not entirely within the Company's control. Therefore, at each reporting date, the Company reassesses the estimated timing of regulatory approval and attainment of sales milestones and the expected contractual success fee payments due therefrom. If the timing and/or amount of such expected payments is materially different than original estimates, the Company will prospectively adjust the accretion of the development financing liability and the imputed interest rate.

The Company identified certain contingent repayment features in the agreement that are required to be bifurcated from the debt host instrument as embedded derivative liabilities; however, the fair value of these features was immaterial at the Effective Date and as of September 30, 2022. The fair value of the embedded derivative liabilities will be assessed at subsequent reporting dates if material.

As of September 30, 2022, the development financing liability was classified as a long-term liability, as the Company expects the related repayments to take place between 2024 and 2030 for purposes of the model used to calculate its carrying value. The imputed interest rate on the unamortized portion of the development financing liability was approximately 18.5% as of September 30, 2022.

5. Stockholders' Equity

Preferred and Common Stock Authorized

The Company is authorized to issue 10,000,000 shares of preferred stock and 200,000,000 shares of common stock as of September 30, 2022 and December 31, 2021.

Sale of Common Stock and Prefunded Warrants

Pursuant to the Company's public equity offering completed in November 2021, the Company issued pre-funded warrants to purchase 3,125,000 shares of common stock at a price of $3.9999 per share. These pre-funded warrants have an exercise price of $0.0001 per share, were fully exercisable upon issuance, and have no expiration date. A holder will not be entitled to exercise any portion of any pre-funded warrant if the holder's ownership of the Company's common stock would exceed 4.99% to 14.99% following such exercise. The Company determined that the pre-funded warrants should be equity classified because they are freestanding financial instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, permit the holders to receive a fixed number of shares of common stock upon exercise, are indexed to the Company's common stock and meet the equity classification criteria. In addition, such pre-funded warrants do not provide any guarantee of value or return. Accordingly, the proceeds from the issuance of the warrants were recorded as additional paid-in capital on the Company's condensed consolidated balance sheet as of September 30, 2022.

None of the pre-funded warrants were exercised since they were issued in November 2021, and therefore remain outstanding as of September 30, 2022.

At-the-Market (ATM) Facility

In July 2020, the Company filed a $200.0 million registration statement on Form S-3 with the SEC and entered into an at-the-market facility (ATM) to sell up to $75.0 million of common stock under the registration statement. To date, the Company has not sold any shares of common stock under the ATM.

6. 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 equivalents outstanding during the period. Pre-funded warrants to purchase 3,125,000 shares of common stock were included in the weighted-average common stock share equivalents outstanding for the three and nine months ended September 30, 2022.

In all periods presented, the Company's outstanding stock options were excluded from the calculation of net loss per share because their effect would be antidilutive. The following table sets forth the computation of basic and diluted net loss per share (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Numerator:				
Net loss	$ (24,505)	$ (22,682)	$ (79,368)	$ (63,455)
Denominator:				
Weighted average number of:				
Common stock shares outstanding	84,679,272	69,022,937	84,678,388	68,985,112
Pre-funded warrants outstanding	3,125,000	—	3,125,000	—
Total	87,804,272	69,022,937	87,803,388	68,985,112
Net loss per share	$ (0.28)	$ (0.33)	$ (0.90)	$ (0.92)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Common stock options	13,960	10,704	13,960	10,704
Incentive awards	101	101	101	101
Total	14,061	10,805	14,061	10,805

7. Stock Plans and Stock-Based Compensation

Stock Plans

As of September 30, 2022, there were 2,650,362 shares available for future grants under the Company's 2013 Equity Incentive Plan and no shares available for grant under the Company's 2020 New Hire Plan. On January 1, 2022, in accordance with the annual share increase provision in the 2013 Plan, the Company added 4,233,896 shares to the 2013 Plan share reserve. During the three and nine months ended September 30, 2022, the Company granted 38,600 and 3,662,868 stock options, respectively, which primarily related to its option grants issued to employees and directors.

Stock-Based Compensation Expense

Stock-based compensation expense is included in the condensed consolidated statements of operations and comprehensive loss and is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	$ 1,052	$ 1,115	$ 3,220	$ 3,343
General and administrative	1,298	1,434	3,936	4,268
Total stock-based compensation expense	$ 2,350	$ 2,549	$ 7,156	$ 7,611

8. Commitments and Contingencies

Genfit Litigation

On January 15, 2021, Genfit S.A. (Genfit) filed a complaint against the Company in the U.S. District Court for the Northern District of California, alleging misappropriation of trade secrets and related causes of action based on the Company's receipt of a Genfit protocol synopsis for Genfit's Phase 3 clinical trial of its drug candidate elafibranor in patients with primary biliary cholangitis. An Amended Complaint was filed on April 16, 2021 with substantially the same allegations. Genfit seeks damages in an unspecified amount as well as injunctive relief. On March 12, 2021, the Court granted a Temporary Restraining Order (later converted to a Preliminary Injunction), prohibiting the Company from accessing or disseminating the protocol synopsis, using any Genfit trade secrets contained therein or destroying any evidence related thereto. The Company filed a Motion to Dismiss the Amended Complaint that was granted on September 9, 2021, with leave to amend. Genfit filed a Second Amended Complaint on October 15, 2021 with substantially the same allegations and claims for relief as in the original complaint. The Company filed a Motion to Dismiss most of the Second Amended Complaint that was granted on January 21, 2022, without further leave to amend. What remains in the complaint is an alleged misappropriation of the protocol synopsis as a whole. The Company filed its Answer to what remained of the Second Amended Complaint on February 4, 2022. The Company intends to defend itself vigorously. While the outcome of any litigation is inherently uncertain, based on currently available information, management does not currently believe a loss associated with this matter is probable, nor is any amount reasonably estimable, and accordingly no amounts have been recorded or disclosed.

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, 2022 are not necessarily indicative of results that may occur in future interim periods or for the full fiscal year.

This Quarterly Report on Form 10-Q contains statements indicating expectations about future performance and other forward-looking statements within the meaning of Section 27A of the Securities Act, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act, that involve risks and uncertainties. Words such as "may," "will," "should," "could," "would," "expect," "plan," "anticipate," "believe," "estimate," "project," "potential," "seek," "target," "goal," "intend," variations of such words, and similar expressions are intended to identify forward-looking statements. These statements appear throughout this Quarterly Report on Form 10-Q and are statements regarding our current expectation, belief, or intent, primarily with respect to our operations and related industry developments. Examples of these statements include, but are not limited to, statements regarding our expectations with respect to the following: our business and scientific strategies; the progress of our product development programs and the timing of results; regulatory submissions and approvals; the impact of the COVID-19 pandemic on our company and operations; our drug discovery technologies; our research and development expenses; protection of our intellectual property; sufficiency of our cash and capital resources and the need for additional capital; and our operations and legal risks. You should not place undue reliance on these forward-looking statements. Our actual results and the timing of events may differ significantly from the results discussed in the forward-looking statements for many reasons. Factors that might cause such a difference include those discussed under the caption "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. These and many other factors could affect our future financial and operating results. We undertake no obligation to update any forward-looking statement to reflect events after the date of this Quarterly Report. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this Quarterly Report on Form 10-Q. While we believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into or review of all relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely on these statements.

Overview

CymaBay Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on developing and providing access to innovative therapies for patients with liver and other chronic diseases with high unmet medical need.

Our lead product candidate, seladelpar, is a potent and selective agonist of peroxisome proliferator activated receptor delta (PPARd), a nuclear receptor that regulates genes directly or indirectly involved in the synthesis of bile acids/sterols, metabolism of lipids and glucose, inflammation, and fibrosis. We have been focused on developing seladelpar for the treatment of primary biliary cholangitis (PBC), an autoimmune disease that causes progressive destruction of the bile ducts in the liver resulting in impaired bile flow (cholestasis) and inflammation.

Seladelpar—Primary Biliary Cholangitis (PBC)

In late 2020, we commenced startup and site feasibility activities for RESPONSE, a global Phase 3 registration study to evaluate seladelpar in patients with PBC. The RESPONSE trial completed enrollment in July 2022 with a total of 193 subjects enrolled in the trial. The RESPONSE trial is a double-blind, randomized, placebo-controlled, 52-week study to evaluate the safety and efficacy of 10 mg of seladelpar versus placebo in patients with PBC who have had an inadequate response to UDCA (defined as a serum alkaline phosphatase level ≥ 1.67 x the upper limit of normal after at least 12 months of treatment) or an intolerance to UDCA to be eligible for the trial. The primary efficacy outcome measure will be the responder rate at 52 weeks in the seladelpar 10 mg group compared to placebo. A responder is defined as a patient who achieves an alkaline phosphatase level < 1.67 x the upper limit of normal with at least a 15% decrease from baseline and has a normal level of total bilirubin. Key secondary outcome measures will include evaluating the effect of seladelpar compared to placebo on normalization of alkaline phosphatase at 52 weeks and on pruritus at 6-months for patients with moderate to severe pruritus at baseline assessed by a numerical rating scale recorded with an electronic diary.

In addition to RESPONSE, we also commenced startup activities in late 2020 for ASSURE, a long-term extension study, which is open to patients who were eligible for our previous long-term extension study that was terminated early in late 2019, including those patients from our previously completed Phase 2 open label study and our Phase 3 ENHANCE study, as well as patients who complete treatment in RESPONSE. The ASSURE trial is continuing to enroll eligible patients and currently has over 180 subjects enrolled. The ASSURE trial is an open-label, long-term study intended to collect additional long-term safety and efficacy data to support registration.

MBX-2982

MBX-2982 targets G protein-coupled receptor 119 (GPR119), a receptor that interacts with bioactive lipids known to stimulate glucose-dependent insulin secretion. In November 2020, we announced a Phase 2a proof-of-pharmacology study to assess whether MBX-2982 can enhance glucagon secretion during insulin-induced hypoglycemia in subjects with T1D. The study is actively enrolling patients. If successful, studies to evaluate MBX-2982 as a potential preventive therapy for hypoglycemia in patients with T1D may be warranted. The study is being led by the AdventHealth Translational Research Institute in Orlando, Florida and is fully funded by The Leona M. and Harry B. Helmsley Charitable Trust. CymaBay retains full commercial rights to MBX-2982. We believe MBX-2982 may also have utility in various inflammatory diseases and we are currently exploring potential opportunities to advance development.

CB-0406

In 2020 we began to evaluate CB-0406, the active metabolite of arhalofenate in a single and multiple ascending dose study in healthy subjects to establish its pharmacokinetics, safety and maximum tolerated dose. While the study showed CB-0406 had improved pharmacokinetics versus arhalofenate, CB-0406's safety profile did not support continued development as a result of the occurrence of a small number of reversible cases of thrombocytopenia at higher doses. Therefore, in mid-2021 we discontinued development of CB-0406.

COVID-19 Pandemic

As a result of the COVID-19 pandemic, we have experienced and may continue to experience disruptions that could impact aspects of our business, including our progress towards the initiation and completion of certain clinical trials, and other associated drug development activities. The emergence of COVID-19 variants, have disrupted, and may continue to disrupt, aspects of our business, in particular in regard to the initiation and operation of clinical trial sites in portions of the United States, in the U.K. and in Europe. Possible future disruptions are currently difficult to foresee. We continue to monitor areas of potential risk which include, but are not limited to, the following:

- Clinical trial and drug manufacturing operations—In collaboration with our clinical research organization partners, we sponsor clinical trials that take place at investigator sites in the U.S. and internationally. We also partner with contract manufacturing organizations to develop, manufacture, and distribute our product candidate drug supplies. To date, these collective research and development personnel and vendors have adapted to COVID-19 related travel restrictions and reduced access to work facilities through the use of remote working technologies and other measures as they continue to progress toward completion of our clinical trials. Although we and our contractors continue to plan for and develop pandemic-related risk mitigation strategies, it is uncertain whether these plans will continue to be sufficient to fully offset the potential impact COVID-19 may have on our ability to execute our development activities in a timely and cost-effective manner.
- Drug regulator interactions—The FDA and comparable foreign regulatory agencies may experience operational interruptions or delays, which could impact timelines for regulatory meetings, submissions, trial initiations, and regulatory approvals.
- Financial reporting and compliance—To date, there has been no adverse impact on our ability to maintain our established financial reporting functions and internal controls over financial reporting. However, our ability to prepare our financial results timely and accurately is partially dependent upon the availability of third-party information systems and other cloud-based services.
- Remote workforce operations—To date, our workforce has adapted to remotely working to maintain operations. Our operations are currently in a hybrid model with most employees working from our office for a portion of the week and working remotely for the rest of the week. Our continued use of partially-remote operations, however, could increase our cyber-security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations, or delay necessary interactions with regulators, contract manufacturers, contract research organizations, clinical trial sites, and other important agencies and contractors, which may result in increased costs to us.

Overall, we cannot at this time predict the specific extent, duration, or full impact that the continuing COVID-19 pandemic will have on our future consolidated financial condition and operations. The impact of the COVID-19 pandemic on our consolidated financial performance will depend on future developments, including emergence of COVID-19 variants, the duration and spread of the pandemic and related governmental advisories and restrictions, which could result in unexpected costs to us. These developments and the impact of COVID-19 on the financial markets and the overall economy are highly uncertain. If the financial markets and/or the overall economy are impacted for an extended period, our results may be adversely affected.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of these condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and disclosure of contingent 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 which we believe to be materially reasonable under the circumstances, the results of which form our basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources, and evaluate our estimates on an ongoing basis. Actual results may materially differ from those estimates under different assumptions or conditions.

There have been no changes to our critical accounting policies since we filed our Annual Report on Form10-K for the year ended December 31, 2021 with the SEC on March 17, 2022. For a description of our critical accounting policies and estimates, please refer to our Annual Report on Form 10-K.

Recent Accounting Pronouncements

Refer to *Note 2—Summary of Significant Accounting Policies* in the notes to our unaudited interim condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q, for a discussion of recent accounting pronouncements.

Results of Operations

General

To date, we have not generated any income from operations. As of September 30, 2022, we have an accumulated deficit of $846.2 million, primarily as a result of expenditures for research and development, general and administrative and interest expenses from inception to that date. All of our product candidates are at various stages of development and will require additional work and regulatory approval before they can be licensed or commercialized. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future and there can be no assurance that we will ever generate sufficient revenue to achieve and sustain profitability. Until we can generate sufficient product revenue, which we may never do, we will need to finance future cash needs through potential collaborative, partnering or other strategic arrangements, as well as through equity offerings, debt financings or a combination of the foregoing.

Operating Results

Our results of operations for the three and nine months ended September 30, 2022 and 2021 are presented below (in thousands):

	Three Months Ended September 30,		Change Q3	Nine Months Ended September 30,		Change Q3 YTD
	2022	2021	2022 vs. 2021	2022	2021	2022 vs 2021
($ in thousands)						
Operating expenses:						
Research and development	$ 15,459	$ 17,010	$ (1,551)	$ 51,765	$ 46,137	$ 5,628
General and administrative	5,904	5,179	725	17,869	16,936	933
Total operating expenses	21,363	22,189	(826)	69,634	63,073	6,561
Loss from operations	(21,363)	(22,189)	826	(69,634)	(63,073)	(6,561)
Other income (expense), net:						
Interest income	677	29	648	1,098	140	958
Interest expense	(3,819)	(522)	(3,297)	(10,832)	(522)	(10,310)
Total other income (expense), net	(3,142)	(493)	(2,649)	(9,734)	(382)	(9,352)
Net loss	$(24,505)	$(22,682)	$ (1,823)	$(79,368)	$(63,455)	$ (15,913)

Research & Development Expenses

Conducting research and development is central to our business model. Research and development expenses decreased $1.6 million to $15.5 million from $17.0 million for the three months ended September 30, 2022 and 2021, respectively. This decrease was due to a reduction in clinical activity due to the completion of enrollment of our clinical trial RESPONSE. Research and development expenses increased $5.6 million to $51.8 million from $46.1 million for the nine months ended September 30, 2022 and 2021, respectively. This increase was largely due to activities associated with the development of seladelpar focusing primarily on our late-stage PBC program. We expect that our research and development expenses will increase in the future due to costs associated with our ongoing late-stage development of seladelpar.

Research and development expenses are detailed further in the table below (in thousands):

	Three Months Ended September 30,		Change Q3	Nine Months Ended September 30,		Change Q3 YTD
	2022	2021	2022 vs 2021	2022	2021	2022 vs. 2021
Project costs:						
Seladelpar PBC clinical studies	$ 7,955	$10,180	$ (2,225)	$26,998	$25,050	$ 1,948
Seladelpar drug manufacturing & development	1,227	1,530	(303)	5,160	3,675	1,485
Seladelpar and non-seladelpar other studies	48	371	(323)	434	2,779	(2,345)
Total project costs	9,230	12,081	(2,851)	32,592	31,504	1,088
Internal research and development costs	6,229	4,929	1,300	19,173	14,633	4,540
Total research and development	$15,459	$17,010	$ (1,551)	$51,765	$46,137	$ 5,628

Our project costs consist primarily of:

- expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and a substantial portion of our preclinical activities;
- the cost of acquiring materials and manufacturing any product for use in clinical trial and other research activities; and
- other costs associated with development activities, including additional studies.

Internal research and development costs consist primarily of salaries and related fringe benefits costs for our employees (such as workers' compensation and health insurance premiums), stock-based compensation charges, travel costs, and overhead expenses. Internal costs generally benefit multiple projects and are not separately tracked per project.

Comparison of the three months ended September 30, 2022 and 2021

Total project costs decreased $2.9 million to $9.2 million from $12.1 million for the three months ended September 30, 2022 and 2021, respectively. The decrease was mostly due to the completion of enrollment of our RESPONSE trial during the three months ended September 30, 2022. Project costs for the three months ended September 30, 2022 and 2021 primarily consisted of seladelpar-related clinical trial expenses for PBC. Internal research and development costs increased by $1.3 million to $6.2 million from $4.9 million for the three months ended September 30, 2022 and 2021, respectively, primarily due to higher employee compensation incurred in the three months ended September 30, 2022 as compared to the three months ended September 30, 2021, as we continued to hire additional research and development personnel to support our clinical studies. As we continue to progress late-stage development of seladelpar in PBC as well as development activities associated with other product candidates, we expect both total project and internal costs to increase in the future.

Comparison of the nine months ended September 30, 2022 and 2021

Total project costs increased by $1.1 million to $32.6 million from $31.5 million for the nine months ended September 30, 2022 and 2021, respectively. Project costs for the nine months ended September 30, 2022 and 2021 primarily consisted of seladelpar-related clinical trial expenses for PBC. These cost increases were primarily driven by an expansion of our site activation, patient enrollment efforts, and other clinical trial activities. Internal research and development costs increased by $4.5 million to $19.2 million from $14.6 million for the nine months ended September 30, 2022 and 2021, respectively, primarily due to higher employee compensation incurred in the nine months ended September 30, 2022 as compared to the nine months ended September 30, 2021, as we continued to hire additional research and development personnel to support our clinical studies.

General and Administrative Expenses

General and administrative expenses consist principally of personnel-related costs, professional fees for legal, consulting, and accounting services, rent, and other general operating expenses not otherwise included in research and development.

Comparison of the three months ended September 30, 2022 and 2021

General and administrative expenses increased by $0.7 million to $5.9 million from $5.2 million for the three months ended September 30, 2022 and 2021, respectively. The increase was driven primarily by an increase in in headcount in general and administrative personnel in the three months ended September 30, 2022 when compared to three months ended September 30, 2021,

as we continue to add administrative personnel and expand our infrastructure in support of our drug development activities. We expect general and administrative expenses to increase in the future as we continue to add administrative personnel and expand our infrastructure in support of our drug development activities.

Comparison of the nine months ended September 30, 2022 and 2021

General and administrative expenses increased by $0.9 million to $17.9 million from $16.9 million for the nine months ended September 30, 2022 and 2021, respectively. The increase was driven primarily by an increase in headcount in general and administrative personnel in the nine months ended September 30, 2022, as we continue to add administrative personnel and expand our infrastructure in support of our drug development activities, partially offset by a reduction in legal and outside consulting-related expenses.

Other Income (Expense), Net

Interest income increased $0.6 million to $0.7 million from an immaterial amount for the three months ended September 30, 2022 and 2021, respectively. Interest income increased $1.0 million to $1.1 million from $0.1 million for the nine months ended September 30, 2022 and 2021, respectively. The increase in interest income was driven primarily by a higher investment portfolio balance compared to the prior year period due to funds that had been received related to our Development Financing Arrangement and November 2021 equity financing.

Interest expense is related to the accretion of the development financing liability recorded in connection with the July 2021 Abingworth Development Financing Agreement using the effective interest method, and increased $3.3 million to $3.8 million from $0.5 million for the three months ended September 30, 2022 and 2021, respectively. The increase in interest expense was driven primarily by an increase in the payments received under the development financing agreement comparatively between periods. Interest expense increased $10.3 million to $10.8 million from $0.5 million for the nine months ended September 30, 2022 and 2021, respectively. The increase was driven primarily by a greater amount of time during which interest was accrued and payments received under the development financing agreement.

Liquidity and Capital Resources

We have financed our operations primarily through the sale of equity securities, licensing fees, issuance of debt and collaborations with third parties. At September 30, 2022, cash, cash equivalents and marketable securities totaled $153.4 million, compared to $194.6 million at December 31, 2021.

Development Financing

On July 30, 2021, (the Effective Date) we entered into a Development Financing Agreement (the Financing Agreement) with Abingworth to obtain funding to support our development of seladelpar for the treatment of PBC. The Financing Agreement provides us up to $100.0 million in funding, of which $25 million was received in August 2021, $25 million was received in November 2021 and $25 million was received in January 2022. In return, we will pay to Abingworth fixed and variable success payments, as further described in *Note 4—Development Financing Agreement* in the notes to our consolidated financial statements. We had an option to receive an additional $25 million within approximately two months of enrollment completion of our Phase 3 RESPONSE clinical trial; however, we did not exercise the option to receive this additional funding.

At-the-Market (ATM) Facility

In July 2020, we filed a $200.0 million registration statement on Form S-3 with the SEC and entered into an at-the-market facility (ATM) to sell up to $75.0 million of common stock under the registration statement. To date, we have not sold any shares of common stock under the ATM.

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,	
	2022	2021
Net cash used in operating activities	$(65,324)	$(55,188)
Net cash (used in) provided by investing activities	(54,341)	72,666
Net cash provided by financing activities	24,550	23,292
Net (decrease) increase in cash and cash equivalents	$(95,115)	$ 40,770

Operating Activities: Net cash used in operating activities for the nine months ended September 30, 2022 increased by $10.1 million to $65.3 million as compared to $55.2 million for the same period in the prior year, primarily due to an increase in our net loss to $79.4 million from $63.5 million in the comparable prior year period due to the expansion of late-stage clinical trial activities related to the seladelpar development program. In addition, cash was used to fund changes in our working capital due to timing of payments.

Investing Activities: Net cash used in investing activities was $54.3 million for the nine months ended September 30, 2022, compared to $72.7 million provided by investing activities for the same period in the prior year, primarily due to the timing of our investments and maturities of marketable securities and portfolio risk management.

Financing Activities: Net cash provided by financing activities was $24.6 million for the nine months ended September 30, 2022, which mostly consisted of a $25.0 million funding payment received from Abingworth under the Development Financing Agreement, which was partially offset by $0.5 million of issuance costs paid for the issuance of common stock from the November 2021 equity financing.

Capital Requirements

We have incurred operating losses since inception and had an accumulated deficit of $846.2 million at September 30, 2022. As of September 30, 2022, we had cash, cash equivalents and marketable securities of approximately $153.4 million, which we believe is sufficient to fund our current operating plan through 2023.

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable to Smaller Reporting Companies.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation as of September 30, 2022 under the supervision and with the participation of our management, including our President and Chief Executive Officer and Vice President, Finance, of the effectiveness of our "disclosure controls and procedures," which are defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), as controls and other procedures of a company that are designed to ensure that the information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our President and Chief Executive Officer and Vice President, Finance, as appropriate, to allow timely decisions regarding required disclosure. Based upon that evaluation, our President and Chief Executive Officer and Vice President, Finance concluded that our disclosure controls and procedures were effective as of September 30, 2022.

Limitations on the Effectiveness of Controls

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the controls are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our President and Chief Executive Officer and Vice President, Finance have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were sufficiently effective to provide reasonable assurance that the objectives of our disclosure control system were met.

Changes in Internal Controls

There were no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2022, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We have not experienced any material impact to our internal controls over financial reporting despite the fact that most of our employees are working in a hybrid remote model due to the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 situation on our internal controls to minimize the impact on their design and operating effectiveness.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

On January 15, 2021, Genfit S.A. (Genfit) filed a complaint against us in the U.S. District Court for the Northern District of California, alleging misappropriation of trade secrets and related causes of action based on our receipt of a Genfit protocol synopsis for Genfit's Phase 3 clinical trial of its drug candidate elafibranor in patients with primary biliary cholangitis. An Amended Complaint was filed on April 16, 2021 with substantially the same allegations. Genfit seeks damages in an unspecified amount as well as injunctive relief. We have stated in pleadings that we did not request or take any steps to obtain Genfit's protocol synopsis, have taken diligent steps to remove and quarantine it, and are not using any Genfit trade secrets in our clinical trials. On March 12, 2021, the court granted a Temporary Restraining Order (later converted to a Preliminary Injunction), prohibiting us from accessing or disseminating the protocol synopsis, using any Genfit trade secrets contained therein or destroying any evidence related thereto. We filed a Motion to Dismiss the Amended Complaint that was granted on September 9, 2021, with leave to amend. Genfit filed a Second Amended Complaint on October 15, 2021 with substantially the same allegations and claims for relief as in the original complaint. We filed a Motion to Dismiss the Second Amended Complaint that was granted on January 21, 2022, without further leave to amend. What remains in the complaint is an alleged misappropriation of the protocol synopsis as a whole. We filed our Answer to what remained of the Second Amended Complaint on February 4, 2022. We intend to defend ourselves vigorously.

Item 1A.

Risk Factors

In addition to the factors discussed elsewhere in this report, the following are important factors that could cause actual results or events to differ materially from those contained in any forward-looking statements made by us or on our behalf. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not currently known to us or that we deem immaterial also may impair our business operations. If any of the following risks or such other risks actually occur, our business could be harmed.

RISK FACTOR SUMMARY

We are subject to a number of risks that if realized could materially harm our business, prospects, operating results, and financial condition. Some of the more significant risks and uncertainties we face include those summarized below. The summary below is not exhaustive and is qualified by reference to the full set of risk factors set forth in Item 1A of this Form 10-Q "Risk Factors." Please carefully consider all of the information in thisForm 10-Q, including the full set of risks set forth in the "Risk Factors" section, and in our other filings with the SEC before making an investment decision regarding CymaBay.

Risks Related to the COVID-19 Pandemic

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

Risks Related to Our Financial Condition and Capital Requirements

- We have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. We may need to raise additional equity and/or debt capital to fund our continued operations, including clinical trials and other product development. In the event we do not successfully raise sufficient funds to finance our product development activities, we will curtail our product development activities commensurate with the magnitude of the shortfall or our product development activities may cease altogether.

- Failure to remain in compliance with our obligations under the development financing agreement with Abingworth could lead to reduced funding under the agreement and/or the acceleration of potentially significant payments to Abingworth.
- Our ability to generate future revenues from product sales is uncertain and depends upon our ability to successfully develop, obtain regulatory approval for, and commercialize product candidates, including most importantly, seladelpar.
- Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Risks Related to Clinical Development and Regulatory Approval

- Drug development and obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain.
- Serious complications or side effects in connection with the use or development of our product candidates could lead to delay or discontinuation of development of our product candidates.

Risks Related to Our Reliance on Third Parties

- Our manufacturing partners and other service providers, including CROs managing our clinical trials, may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates and future products.

Risks Related to Commercialization of Our Product Candidates

- We have never successfully commercialized a product. If any of our product candidates receive marketing approval, they may nonetheless be unable to gain sufficient market acceptance by physicians, patients, health care payors and others in the medical community.
- If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.
- The commercial success of our products is subject to significant competition from products or product candidates that may be superior to, or more cost effective than, our products or product candidates.

Risks Related to Our Intellectual Property

- We may not be able to protect the confidentiality of our trade secrets, and our patents or other means of defending our intellectual property may be insufficient to protect our proprietary rights.
- Patents or proprietary rights of others may restrict our development, manufacturing, and/or commercialization efforts and subject us to litigation and other proceedings that could find us liable for damages.

Other Risks Factors—Risks Related to Employees, Information Technology, and Owning Our Common Stock

- Our business is dependent on our key personnel and will be harmed if we cannot recruit and retain leaders in our development, administrative, and commercial organizations.
- Significant disruptions of information technology systems or breaches of data security could adversely affect our business.
- Changes in and failures to comply with United States and foreign privacy and data protection laws, regulations and standards may adversely affect our business, operations and consolidated financial performance.
- 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.

Risks Related to the COVID-19 Pandemic

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

While the COVID-19 pandemic did not materially adversely affect our business operations in the three and nine months ended September 30, 2022, economic and health conditions in the United States and across most of the globe have continued to change. The emergence of COVID-19 variants have further disrupted the global economy. As a result of the COVID-19 pandemic, including the emergence of new variants, we have experienced and may continue to experience disruptions that could impact aspects of our business, including our progress towards the completion of our clinical studies and other associated drug development activities. Possible future disruptions are currently difficult to foresee and include, but are not limited to, potential risk areas as noted below:

- We are currently managing clinical trials in geographies that are affected by the COVID-19 pandemic. While we have not experienced material impacts to our clinical activities through September 30, 2022, we are observing impacts due to COVID-19, including reluctance of subjects to enroll in clinical studies due to the ongoing pandemic, travel restrictions impacting study personnel and trial participants, personnel shortages at clinical sites and operations and facility restrictions impacting trial operations. We believe that the COVID-19 pandemic, including the emergence of COVID-19 variants, will have a continuing impact on various aspects of our clinical activities in the future. For example, pandemic-related reluctance or restrictions, including curtailment of activities, could reduce the rate of patient enrollment in our clinical trials, and impair the ability to efficiently treat patients at investigator sites. Additionally, our employees, representatives from our clinical research organization partners, and study investigators may be required to delay, or alter, their approach to complete work on our trials.
- We have moved to a hybrid model of operations, with most employees working from our office for a portion of the week and working remotely for the rest of the week. The safety, health and well-being of our workforce is of primary concern and we may need to enact further precautionary measures to help minimize the risk of our employees being exposed to the coronavirus.
- Our continuing reliance on personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. In addition, this could increase our cyber-security and data privacy risks, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations, or delay necessary interactions with regulators, contract manufacturers, contract research organizations, clinical trial sites, and other important agencies and contractors, which could result in increased costs to us.
- In some jurisdictions, contractors involved in conducting our research and development activities may not be able to access their applicable work facilities for an extended period of time as a result of facility closure orders and the possibility that governmental authorities further modify such access restrictions.
- The United States Food and Drug Administration (FDA), comparable foreign regulatory agencies, and ethics boards may experience operational interruptions or delays, which could impact timelines for regulatory meetings, submissions, trial initiations, and regulatory approvals.

The COVID-19 pandemic continues to evolve. The emergence of COVID-19 variants may also continue to affect the impact of the pandemic. The extent to which the pandemic may impact our business, including our preclinical, clinical and associated drug development activities, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of COVID-19, variants to COVID-19 that continue to arise and their relative transmissibility and virulence, the duration of the pandemic, travel restrictions and actions to contain the pandemic or treat its impact, such as social distancing and quarantines or lock-downs in the United States, particularly in the San Francisco Bay Area where our executive offices are located, and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

Risks Related to Our Financial Condition and Capital Requirements

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

We have incurred significant net losses since our inception. We anticipate that we will continue to incur significant losses for the foreseeable future, and we may never achieve or maintain profitability. As of September 30, 2022, we had cash, cash equivalents and marketable securities of approximately $153.4 million. On July 30, 2021, we entered into a Development Financing Agreement with an affiliate of Abingworth LLP pursuant to which Abingworth has committed to provide us up to $100.0 million in funding, of which we have already received $75 million. In November 2021, we sold 15,625,000 shares of common stock at $4.00 per share and pre-funded warrants to purchase 3,125,000 shares of common stock at $3.9999 per share in a public equity offering, for total gross offering proceeds of approximately $75 million, before deducting the underwriting fees and other offering expenses. We may need to raise additional equity and/or debt capital to fund our continued operations, including clinical trials and other product development. We may also choose to raise additional equity and/or debt capital if appropriate opportunities become available. Our monthly spending levels vary based on new and ongoing development and corporate activities. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete.

In the event we do not successfully raise sufficient funds to finance our product development activities, we will curtail our product development activities commensurate with the magnitude of the shortfall or our product development activities may cease altogether. To the extent that the costs of ongoing development exceed our current estimates and we are unable to raise sufficient additional capital to cover such additional costs, we will need to reduce operating expenses, sell assets, enter into strategic transactions, or effect a combination of the above. No assurance can be given that we will be able to enter into any of such transactions on acceptable terms, if at all.

Our future funding requirements and sources will depend on many factors, including but not limited to the following:

- the rate of progress and cost of our clinical studies;
- the need for additional or expanded clinical studies;
- the rate of progress and cost of our Chemistry, Manufacturing and Control development, registration, validation and commercial programs;
- the timing, economic and other terms of any licensing, collaboration or other similar arrangement into which we may enter;
- the costs and timing of seeking and obtaining FDA and other regulatory approvals;
- the extent of our other development activities;
- the costs of filing, prosecuting, defending and enforcing our 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 would have a material adverse effect on our business, operating results, prospects, and on our ability to develop our product candidates.

Failure to remain in compliance with our obligations under the development financing agreement with Abingworth could lead to reduced funding under the agreement and/or the acceleration of potentially significant payments to Abingworth.

On July 30, 2021, we entered into a Development Financing Agreement (the Financing Agreement) with Abingworth, pursuant to which Abingworth agreed to provide funding to us to support our development of seladelpar for the treatment of PBC. Pursuant to the Financing Agreement, Abingworth funded $75 million through November 2022. Pursuant to the Financing Agreement, we will be required to use commercially reasonable efforts to develop seladelpar and complete our development program in accordance with the Financing Agreement and an agreed timeline. In return, we will pay to Abingworth (1) upon the first to occur of regulatory approval of seladelpar for the treatment of PBC in the U.S., U.K., Germany, Spain, Italy or France (Regulatory Approval), fixed success payments equal to 2.0x of the funding provided and (2) variable success payments equal to 1.1x of the funding provided upon first reaching certain U.S. product sales milestones. At the time that Abingworth receives, collectively, an aggregate of 3.1x of the funding provided, our payment obligations under the Financing Agreement will be fully satisfied.

The Financing Agreement terminates upon the payment of all payments owing to Abingworth, unless earlier terminated. The Agreement may be earlier terminated in a number of circumstances including (i) by Abingworth if we fail to use commercially reasonable efforts to develop seladelpar as set forth in the Financing Agreement or if we fail to make required payments (Fundamental Breach) or (ii) by either party if the other party materially breaches the Agreement (Material Breach). In certain instances, upon the termination of the Financing Agreement, we will be obligated to pay Abingworth a multiple of the amounts paid to us under the Agreement, including specifically,

(i) 310% of such amounts in the event that Abingworth terminates the agreement due to (x) a Fundamental Breach, (y) our bankruptcy, or (z) a safety concern resulting from gross negligence on our part or due to a safety concern that was material on the Effective Date and the material data showing such safety concern was not publicly known, disclosed to Abingworth, or in the diligence room made available to Abingworth,

(ii) 200% of such amounts in the event the Agreement is terminated due to (x) our Material Breach or (y) the security interests of Abingworth being invalidated or terminated other than as set forth in the Financing Agreement, and

(iii) 100% of such amounts in the event of certain irresolvable disagreements within the executive review committee overseeing our development of seladelpar.

In addition, if, following certain terminations, we continue to develop seladelpar for the treatment of PBC and obtain Regulatory Approval, we will make the payments to Abingworth as if the Financing Agreement had not been terminated, less any payments made upon termination.

The payments required under the Financing Agreement are significant. Failure to generate sufficient revenue to make such payments if and as they become due, or failure to otherwise finance such payments would have a material adverse effect on our business. In addition, if we are unable to comply with our obligations under the Financing Agreement and/or one of the termination events described above occurs, Abingworth may be relieved of their obligation to provide further funding under the Financing Agreement and our payments obligations thereunder may be accelerated. The acceleration of payments under the Financing Agreement would have a material impact on our business and we may not be able to make such payments at such time.

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

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

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

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

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. We do not have any committed external source of funds. If appropriate opportunities become available, we may seek to raise additional equity and/or debt capital to fund our continued operations, including clinical trials and other product development.

To raise additional funds to support our operations, we may sell additional equity or debt securities, enter into collaborations, strategic alliances, or licensing arrangements or other marketing or distribution arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interests of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of stockholders. Debt financing, if

available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, and declaring dividends, and may impose limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

If we raise additional funds through collaborations, strategic alliances, licensing arrangements or other marketing or distribution arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us.

If we are unable to expand our operations or otherwise capitalize on our business opportunities, our business, financial condition and results of operations could be materially adversely affected. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts, or grant others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Risks Related to Clinical Development and Regulatory Approval

We depend on the success of our product candidates and we may not obtain regulatory approval or successfully commercialize our product candidates.

We have not marketed, distributed or sold any products. The success of our business depends upon our ability to develop and commercialize our product candidates. The success of any product candidate will depend on many factors, including the following:

- successful enrollment and completion of clinical trials, including, in the case of RESPONSE, sufficient subjects that receive liver biopsies;
- receipt of marketing approvals from the FDA and regulatory authorities outside the United States for the product candidate;
- establishing commercial manufacturing capabilities by making arrangements with third-party manufacturers;
- launching commercial sales of the product, whether alone or in collaboration with others;
- acceptance of the product by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- a continued acceptable safety profile of the product following marketing approval; and
- obtaining, maintaining, enforcing and defending intellectual property rights and claims.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidate, which would materially harm our business.

We depend on the successful completion of clinical trials for our product candidates.

Before obtaining regulatory approval for the sale of our product candidates, we must complete our current clinical trials as well as potentially additional clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

We may experience a number of unforeseen events during clinical trials for our product candidates, including seladelpar, that could delay or prevent the commencement and/or completion of our clinical trials, including the following:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the clinical study protocol may require one or more amendments delaying study completion;

- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, we may have to compete with other clinical trials to enroll eligible subjects, or subjects may drop out of these clinical trials at a higher rate than we anticipate;
- the number of patients in our RESPONSE clinical trial that receive biopsies may be insufficient to satisfy regulatory requirements;
- clinical investigators or study subjects may 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;
- geo-political turmoil between Russia and Ukraine and/or continuing military actions in Ukraine may cause us to have to wind down clinical trials of seladelpar in Russia or in other countries;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our clinical trial materials or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators to suspend or terminate the trials.

Because successful development of product candidates is uncertain, we are unable to estimate the actual funds required to complete research and development and commercialize our products under development.

Negative or inconclusive results of our future clinical trials of product candidates could cause the FDA or other regulatory authorities to require that we repeat or conduct additional clinical studies. If later stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for our product candidates may be adversely impacted.

Geo-political turmoil between Russia and Ukraine and continuing military actions in Ukraine have caused us to suspend clinical trial activity in Ukraine and wind down clinical trial activity in Russia.

We have a small number of clinical sites in Russia in our RESPONSE clinical trial and in our ASSURE clinical trial. Because of continuing military action in Ukraine we suspended all clinical trial activity in Ukraine. Ongoing geo-political turmoil and continuing military action in the region, together with widening sanctions imposed on Russia, have also caused us to begin to wind down clinical trial activity in Russia. We expect clinical trial activity in Russia for the ASSURE clinical trial to terminate in early 2023 and for the RESPONSE clinical trial in mid-2023. The ongoing military action and sanctions may still affect our RESPONSE and ASSURE clinical trials in Russia prior to wind down. Shipments of seladelpar to Russia may become difficult, delayed or impossible. Shipments of clinical samples from Russia may also become difficult, delayed or impossible. In addition, sites, site personnel and patients may not be able to continue in the trials and we may need to suspend or terminate the trials in Russia prior to the end of our expected wind down. While we have only a small number of clinical sites and enrolled patients in Russia, these disruptions and potential suspensions could complicate the analysis of data from subjects in Russia.

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

Clinical testing is expensive, difficult to design and implement, can take many years to complete, and is uncertain as to outcome. We may experience delays in clinical trials at any stage of development and testing of our product candidates and any delay could result in increased costs to us. Any clinical trials we undertake may not begin on time, have an effective design, enroll a sufficient number of subjects, or be completed on schedule, if at all. The impact of the ongoing COVID-19 pandemic is also uncertain, and may create additional delays in completing our clinical trials.

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

- reluctance of patients to enroll in our clinical trials due to the COVID-19 pandemic;
- personnel shortages at clinical sites due to the COVID-19 pandemic that impact the enrollment timeline or operations at clinical trial sites participating in our clinical trials;
- competition for eligible patients from competing clinical trials;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA or other regulatory authorities on final trial design;
- imposition of a clinical hold following a reported safety event;
- an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical trial sites;
- delays in obtaining required institutional review board (IRB) approval at each site;
- delays in recruiting suitable patients to participate in a trial;
- delays in having subjects complete participation in a trial or return for post-treatment follow-up;
- delays caused by the need to enroll additional subjects that have biopsies in the RESPONSE trial;
- delays caused by subjects dropping out of a trial due to side effects or otherwise;
- changes to treatment guidelines or the introduction of a new standard of care;
- delays caused by clinical sites dropping out of a trial;
- time required to add new clinical sites;
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials; and
- delays in importing clinical trial materials into foreign countries where our clinical trials are being conducted.

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

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

In May 2016, we announced results of a High Dose Phase 2 clinical study of seladelpar in patients with PBC. During the course of this trial three cases of asymptomatic, reversible transaminase elevations occurred, and we made the decision to discontinue the study early after review of safety and efficacy data demonstrated a need for further dose reduction to optimize clinical safety and efficacy. The emergence of adverse events (AEs) and histological observations in subsequent seladelpar clinical trials could prevent us from further developing seladelpar or could result in the denial of regulatory approval.

Furthermore, if any of our approved products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including the following:

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution in a form of a risk evaluation and mitigation strategy (REMS) plan;
- regulatory authorities may require the addition of labeling statements, such as black box or other warnings or contraindications that could diminish the usage of the product or otherwise limit the commercial success of the affected product;
- we may be required to change the way the product is administered or to conduct additional clinical studies;

- we may choose to discontinue sale of the product;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer.

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

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

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

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

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

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

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

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

- the data collection from clinical studies of our product candidates may not be sufficient to support the submission of a new drug application (NDA), marketing authorization or other equivalent submission, or to obtain regulatory approval in the United States or elsewhere.

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

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

Even if we obtain regulatory approval in the United States, the FDA may still impose significant restrictions on the indicated uses or marketing of our products or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. Our products would be subject to additional ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping and reporting of safety and other post-market information. The holder of an approved NDA is obligated to monitor and report AEs and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. Furthermore, promotional materials must be approved by the FDA prior to use for any drug receiving accelerated approval.

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

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

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

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

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. If we are found to have improperly promoted our products for off-label uses, we may become subject to significant fines and other liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for our product candidates, physicians may nevertheless prescribe such products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant government fines and other related liability. For example, the federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA also has requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Even if we obtain FDA approval for our product candidates in the United States, we may never obtain approval for or commercialize our product candidates outside of the United States, which would limit our ability to realize their full market potential.

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

Coverage and adequate reimbursement may not be available for our future products, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any products that we commercialize will depend in part on the extent to which coverage and adequate reimbursement will be available from third-party payers, including government health administration authorities, managed care organizations and private health insurers. Third-party payers decide which therapies they will pay for and establish reimbursement levels. Third-party payers in the United States often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any products that we develop will be made on a payer-by-payer basis. One payer's determination to provide coverage for a drug does not assure that other payers will also provide coverage and adequate reimbursement for the drug. Additionally, a third-party payer's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Third-party payers are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We cannot be sure that coverage and reimbursement in the United States or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

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

Health care professionals and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, third-party payors and customers may expose us to broadly applicable fraud and abuse and other health care laws and regulations that may constrain the business or financial arrangements and relationships through which we research, as well as market, sell and distribute our products. Restrictions under applicable federal and state health care laws and regulations, include the federal Anti-Kickback Statute, the federal False Claims Act, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, the federal false statements statute, the federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or PPACA, commonly referred to as the Physician Payments Sunshine Act, and analogous state laws and regulations, such as state anti-kickback and false claims laws.

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

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

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

For example, the PPACA was enacted to broaden access to health insurance, reduce or constrain the growth of health care spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Since its enactment there have been judicial and Congressional challenges to certain aspects of the PPACA as well as efforts to repeal or replace certain aspects of the PPACA. For example, Congress considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the PPACA. It is unclear how litigation, and the healthcare reform measures of the Biden administration will impact the PPACA and our business.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. In addition, there have been several recent congressional inquiries, proposed bills and other proposals designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products including instituting reference pricing. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. However, it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We are not sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

Risks Related to Our Reliance on Third Parties

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

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

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

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

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

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

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

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

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

- the inability to meet our product specifications, including product formulation, and quality requirements consistently;
- a delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues, including those related toscale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- a failure to comply with cGMP and similar quality standards;
- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- the reliance on a limited number of sources, and in some cases, single sources for key materials, such that if we are unable to secure a sufficient supply of these key materials, we will be unable to manufacture and sell our products in a timely fashion, in sufficient quantities or under acceptable terms;
- the lack of qualified backup suppliers for those materials that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier;
- disruption of the distribution of chemical supplies between the U.K. and E.U. due to Brexit;
- carrier disruptions or increased costs that are beyond our control; and
- the failure to deliver our products under specified storage conditions and in a timely manner.

Any of these events could lead to delays in any clinical study we may undertake, 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 clinical programs for our product candidates, as well as the execution of nonclinical studies. We control only certain aspects of our CSPs' activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CSPs does not relieve us of our regulatory responsibilities.

We and our CSPs are required to comply with the FDA's guidance, which follows the International Council for Harmonization Good Clinical Practice (ICH GCP), which are regulations and guidelines enforced by the FDA for all of our product candidates in clinical development. The FDA enforces the ICH GCP through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CSPs fail to comply with the ICH GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. Our CSPs are not our employees, and we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and nonclinical programs. These CSPs may also have relationships with other entities, including our competitors, for whom they may also be conducting clinical studies, or other drug development activities that could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our confidential information, including our intellectual property, by CSPs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology, among other things. If our CSPs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates that we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

Risks Related to Commercialization of Our Product Candidates

The commercial success of any product will depend upon the acceptance of these products by the medical community, including physicians, patients and health care payors.

If any of our product candidates receive marketing approval, they may nonetheless be unable to gain sufficient market acceptance by physicians, patients, health care payors and others in the medical community. If 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 products 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;
- 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 products 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;
- acceptance of the product by physicians, other health care providers and patients as a safe and effective treatment;
- the potential and perceived advantages of products over alternative treatments;
- the timing of market introduction of competitive products;
- pricing and cost-effectiveness;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- our ability to obtain formulary approval;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement, which may vary from country to country; and
- the effectiveness of our or any future collaborators' sales, marketing and distribution efforts.

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

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

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

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

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

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

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

If our product candidates are approved for commercialization outside the United States, we expect that we will be subject to additional risks related to international operations, including the following:

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

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

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

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

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

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

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

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 products commercially. An individual or a group of individuals may bring a liability claim against us if one of our product candidates causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in the following:

- decreased demand for our products;
- 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 products; and
- loss of revenues.

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

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

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

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

Risks Related to Our Intellectual Property

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

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own, co-own or in-license may fail to result in issued patents with claims that cover the products in the United States or in other countries. If this were to occur, early generic competition could be expected against our products. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which if it exists could be used to invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, third parties may challenge their validity, enforceability, scope or ownership, which may result in such patents, or our rights to such patents, being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the patent applications we hold or license with respect to our product candidates fail to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us and threaten our ability to commercialize our products. We cannot offer any assurances about which, if any, patents will issue or whether any issued patents will be found invalid or unenforceable, will be challenged by third parties or will adequately protect our products. Further, if we encounter delays in development or regulatory approvals, the period of time during which we could market our products under patent protection could be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file any patent application related to our product candidates. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be started 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 proprietaryknow-how that is not patentable, processes for which patents are difficult to enforce and other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we expect all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed, that such agreements provide adequate protection and will not be breached, that our trade secrets and other confidential proprietary information will not otherwise be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

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

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

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

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

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

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

We are a party to a number of technology licenses that are important to our business and may enter into additional licenses in the future. For example, we rely on an exclusive license to certain patents and know-how from Janssen Pharmaceutical NV (Janssen NV), which include seladelpar and certain other PPARd compounds (the PPARd Products). Under the exclusive license with Janssen NV we have full control and responsibility over the research, development and registration of any PPARd Products and are required to use diligent efforts to conduct all such activities. If we fail to comply with our obligations under our agreement with Janssen NV, including our obligations to expend more than a de minimis amount of effort and resources on the research and/or development of at least one PPARd Product, to make any payment called for under the agreement, not to disclose anynon-exempt confidential information related to the agreement, or to use diligent efforts to promote, market and sell any PPARd Product under the agreement, such action would constitute a default under the agreement and Janssen NV may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license, including in the case of the Janssen NV license, seladelpar, which would have a materially adverse effect on our business.

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

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

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in a litigation 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 litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

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

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

Risks Related to Our Business Operations and Industry

Our business could be negatively affected as a result of the actions of activist or hostile stockholders.

Our business could be negatively affected as a result of stockholder activism, which could cause us to incur significant expense, hinder execution of our business strategy, and impact the trading value of our securities. For example, on April 27, 2020, a stockholder filed a preliminary proxy statement containing proposed opposition to our preliminarily filed proxy statement on April 27, 2020, including a proposal to elect three new directors to our Board of Directors and a proposal not to increase to the number of shares of common stock authorized for issuance. While this proxy contest was subsequently suspended, stockholder activism could recur and requires significant time and attention by management and the Board of Directors, potentially interfering with our ability to execute our strategic plan. Stockholder activism could give rise to perceived uncertainties as to our future direction, adversely affect our relationships with key executives and business partners, and make it more difficult to attract and retain qualified personnel. Also, we may be required to incur significant legal fees and other expenses related to activist stockholder matters. Any of these impacts could materially and adversely affect our business and operating results. Further, the market price of our common stock could be subject to significant fluctuation or otherwise be adversely affected by stockholder activism.

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

We are dependent on principal members of our executive team. While we have entered into employment offer letters with each of our executive officers, any of them could leave our employment at any time, as all of our employees are “at will” employees. We do not maintain “key person” insurance for any of our executives or other employees. Recruiting and retaining other qualified

employees for our business, including clinical, scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. We also experience competition from universities, competitors and research institutions for the hiring of scientific and clinical personnel. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. In addition, failure of any of our clinical studies may make it more challenging to recruit and retain qualified personnel. If we are unable to successfully recruit key employees or replace key executives or key employees, it may adversely affect the progress of our research, development and commercialization objectives.

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

As we continue to build our clinical and drug development operations, we will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As we continue to build our clinical development programs, we are expanding our employee base to increase our managerial, clinical, scientific, and other operational teams. Such growth imposes additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a greater amount of attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among current employees. Our expected growth could require greater capital expenditures and may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to create value and/or generate revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to develop and commercialize seladelpar and other potential product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Significant disruptions of information technology systems or breaches of data security could materially adversely affect our business, results of operations and financial condition.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business, particularly in view of the ongoing COVID-19 pandemic and remote work schedule. In the ordinary course of our business, we collect, store and transmit confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have established physical, electronic and organizational measures to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization.

The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems and security vulnerabilities could be significant, and our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event is to occur and cause interruptions in our operations or our vendors, it may result in a material disruption of our product development programs and our reputation could be materially damaged. We could also be exposed to a risk of loss or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

Changes in and failures to comply with United States and foreign privacy and data protection laws, regulations and standards may adversely affect our business, operations and consolidated financial performance.

We are subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, retention, and security of personal data, such as information that we collect about patients and healthcare providers in connection with clinical trials in the United States and abroad. The global data protection landscape is rapidly evolving, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, affect our or our vendors' ability to operate in certain jurisdictions or to collect, store, transfer, use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. In many jurisdictions, enforcement actions and consequences for noncompliance are rising.

In the United States, HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. In the event that we are subject to HIPAA or other United States privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. Many countries in these regions have established or are in the process of establishing privacy and data security legal frameworks with which we, our customers, or our vendors must comply. For example, the EU has adopted the General Data Protection Regulation (EU) 2016/679, or GDPR, which went into effect in May 2018 and introduces strict requirements for processing the personal information of EU subjects, including clinical trial data. The GDPR has increased compliance burdens on us, including by mandating potentially burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and process information about them. The processing of sensitive personal data, such as physical health condition, has imposed heightened compliance burdens under the GDPR and is a topic of active interest among foreign regulators. In addition, the GDPR provides for robust regulatory enforcement and fines for a noncompliant company. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

Risks Relating to Owning Our Common Stock

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

Our common stock was formerly listed on the Nasdaq Capital Market and since the second quarter of 2018 it has been trading on the Nasdaq Global Select Market under the symbol "CBAY". The historical trading prices of our common stock on the Nasdaq Capital Market and the Nasdaq Global Select Market may not be indicative of the price levels at which our common stock will trade in the future, and we cannot predict the extent to which investor interest in us will continue to support an active public trading market for our common stock or how liquid will be that public market.

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

The historical trading price of our common stock has been volatile. Our stock price may continue to be subject to wide fluctuations in response to a variety of factors, including:

- delays in completing the RESPONSE clinical trial or our other clinical trials;
- adverse or inconclusive results in our clinical trials;
- adverse or inconclusive results or delays in preclinical testing;
- inability to obtain additional funding;
- any delay in filing an Investigational New Drug (IND) application or NDA for any of our future product candidates and any adverse development or perceived adverse development with respect to the FDA's review of an IND or NDA;
- failure to enter into new collaborations;

- failure by us or our licensors to prosecute, maintain or enforce our intellectual property rights;
- failure to successfully develop and commercialize our future product candidates;
- changes in laws or regulations applicable to future products;
- changes in the structure of health care payment systems;
- inability to obtain adequate product supply for our 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 or our competitors;
- announcements of significant or potential equity or debt sales by us;
- announcements of clinical trial plans or results by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future; and
- trading volume of our common stock.

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

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

Significant additional capital may be needed in the future to continue our product development efforts in current and future clinical trials and operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If in the future we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. These sales may also result in new investors gaining rights superior to our existing stockholders. Pursuant to our equity incentive plans, we are 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, 2022 was 2,650,362 shares.

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

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

General Risks

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

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

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

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

Item 6. Exhibits

Exhibit No.	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, and incorporated here by reference.)
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation (Filed with the SEC as Exhibit 3.1 to our Current Report on Form 8-K, filed with the SEC on June 26, 2020, SEC File No. 001-36500), and incorporated here by reference.
3.3	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, and incorporated here by reference.)
4.1	Reference is made to Exhibits 3.1, 3.2 and 3.3.
10.1#	PPARd License Agreement, dated June 20, 2006, by and between Metabolex, Inc. and Janssen Pharmaceutica NV
10.2	Controlled Equity Offering℠ Sales Agreement, or sales agreement, dated July 2, 2020, between the registrant and Cantor Fitzgerald & Co. (Filed with the SEC as Exhibit 1.2 to our Registration Statement on Form S-3, filed with the SEC on July 2, 2020, SEC File No. 333-239670, and incorporated here by reference).
31.1	Certification of President and Chief Executive Officer (Principal Executive Officer) pursuant to Rule 13-a-14(a) or Rule 15(d)-14(a) of the Exchange Act.
31.2	Certification of Vice President, Finance (Principal Financial Officer) pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Exchange Act.
32.1	Certification of President and Chief Executive Officer (Principal Executive Officer) and Vice President, Finance (Principal Financial Officer) pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Document
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in exhibit 101)

Certain portions of this exhibit have been omitted because the omitted portions are both not material and is the type of information that CymaBay treats as private or confidential.

SIGNATURES

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

CYMABAY THERAPEUTICS, INC.

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

Date: November 14, 2022

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

Date: November 14, 2022

CERTAIN INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE OF INFORMATION THAT CYMABAY TREATS AS PRIVATE OR CONFIDENTIAL.

Exhibit 10.1

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

1.14 "Metabolex Patents" means all Patents (other than PPAR-d 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-d Compound or a PPAR-d 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-d 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-d Products where the PPAR-d 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-d 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-d Products will be consistent with Metabolex's and its Affiliates' usual course of dealing with all its products other than the PPAR-d 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-d Product is sold in the form of a combination product containing both a PPAR-d Product and one or more independently therapeutically active pharmaceutical molecules that are not PPAR-d Products (for the purpose of this Section 1.16, a "**Combination Product**"), [*].

[*]

If Metabolex (or its Affiliate) sublicenses the development and/or commercialization of a PPAR-d 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-d 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-d 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-d Product) containing a Selective PPAR-d 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-d Product in an extended human patient population designed to obtain data determining efficacy and safety of the PPAR-d 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-d Compound" means: (a) any of the compounds known as [*] (each as described in **Exhibit B**); (b) any other compound that is a Selective PPAR-d Modulator [*] as defined in: [*], or [*] or [*], and/or [*]; and (c) any [*] of any of the foregoing compounds.

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

1.22 "PPAR-d 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-d Compound, or the manufacture or use of a PPAR-d Compound, including without limitation those listed on **Exhibit C**. In addition, "PPAR-d 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-d Product as it exists as of the Effective Date.

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

1.24 "PPAR-g 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-d Compounds or PPAR-d 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-d Product in the particular regulatory jurisdiction.

1.27 "Selective PPAR-d Modulator" means any small molecule compound that (a) [*] interacts with the PPAR-d receptor to [*] or [*], and (b) shows activity toward [*] the PPAR-d receptor in the [*] assay using [*] (or any [*] thereof). To constitute a Selective PPARd 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-d 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.

1.31 "Valid Claim" means (i) a valid and enforceable claim of an issued, unexpired PPAR-d Patent, or (ii) a claim in any pending application for a PPAR-d 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-d Patents and PPAR-d Know-How solely to research, develop, use, market, offer for sale, sell, import, manufacture, have manufactured, and distribute the PPAR-d 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-d 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-d 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-d Patents or PPAR-d 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-d Patents or PPAR-d 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-d 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-d 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.

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-d Product or PPAR-d 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-d Compound), or product that contains a compound (other than a PPAR-d 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-d 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-d 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-d 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-d Products. Metabolex shall provide to Janssen on a semi-annual basis a summary of the development efforts being conducted on PPAR-d 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-d 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-d Product).

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

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-d 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-d 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-d 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-d 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-d 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-d 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-d Know-How that Metabolex may have regarding regulatory matters for PPAR-d 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-d Products. Metabolex will plan, control, carry out and fund all activities related to the promotion, marketing and sale of any PPAR-d Products. Metabolex shall use Diligent Efforts to market, promote and commercialize any and all PPAR-d 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-d 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-d Products.

3.8 Commercialization Costs. Metabolex shall be responsible for all costs and expenses associated with its commercialization activities, including manufacturing of PPAR-d 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-d 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-d 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-d 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-d 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-d Right of First Negotiation (the "**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-**d **License Agreement"**) under which Janssen would receive an exclusive license to the PPAR-d Product or Other Product (as the case may be) on commercially reasonable terms, taking into account the stage of development of the PPAR-d Product or Other Product at the time of such negotiations and Metabolex's prior efforts and resources expended in developing the PPAR-d 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-d 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-d 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-d 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-d 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-d Compounds and PPAR-d 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-d Compound (and associated PPAR-d 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-d Compound, PPAR-d Know-How, PPAR-d Patent, and PPAR-d 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**.

(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-d Patents and PPAR-d 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-d Products and PPAR-d Compounds.

ARTICLE 4

PAYMENTS

4.1 Royalties.

(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-d 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-d Product in such country and (ii) the expiration of the last to expire Valid Claim of a PPAR-d Patent covering such PPAR-d Compound or PPAR-d 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-d Product in any country where such PPAR-d 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-d 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-d 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-d Product in the applicable country, of an amount equal to [*] the royalty paid to such Third Party based upon the sales of the PPAR-d 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-d Product, (ii) the Generic Products each contain the PPAR-d Compound in the PPAR-d Product, or any [*] of such PPAR-d Compound; and (iii) sales of the Generic Products [*] in such country [*], the royalty owed under Section 4.1 for such PPARd Product shall be determined under the following formula: The contribution of sales of such PPAR-d 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-d Product regardless of the number of Patents pertaining thereto.

4.4 Sublicenses. In the event Metabolex grants licenses or sublicenses to others to sell PPAR-d 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-d 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-d Products have been sold, Metabolex shall deliver to Janssen a written report of the amount of gross sales of each PPAR-d 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-d 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.

(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-d 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-d 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-d Patent and Janssen is not abandoning such PPAR-d Patent in favor of another PPAR-d 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 Controlled by Janssen, then Janssen shall provide Metabolex the opportunity to assume responsibility for prosecuting and maintaining such PPAR-d 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-d Patent, then [*] such PPAR-d 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-d 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-d 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-d 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-d Patent or PPAR-d Know-How used in connection with this Agreement.

(b) PPAR-d Patents. If any PPAR-d 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-d Compound, which manufacture, use or sale is likely to have a material adverse effect on current or future sales of any PPAR-d 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-d 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-d 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-d 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-d Patent, that is not a Field Infringement. Notwithstanding the foregoing, in any such action or suit involving a PPAR-d 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-d 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.

(e) Assistance. In the event of any patent infringement litigation involving a PPAR-d 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-d 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-d Compound or PPAR- d

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-d 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.

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-d 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-d Products as permitted under this Agreement;

(b) Regulatory filings relating to PPAR-d 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 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-g 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-d 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;

(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-d Compound, PPAR-d 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-d Patents or PPAR-d 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-d Patents and PPAR-d 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-d 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-d COMPOUNDS AND PPAR-d PRODUCTS 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 ANY WARRANTY THAT THE USE OF PPAR-d 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-d Products and/or PPAR-d 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.

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-d Product-by-PPAR-d 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-d Product. Thereafter, the licenses granted to Metabolex in Section 2.1 as to such PPAR-d 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.

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-d 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-d 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-d 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-d 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-d Products due to either:

(i) financial constraints that have caused Metabolex to delay its PPAR-d 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-d 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-d 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-d Products and PPAR-d 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 a PPAR-d Compound or PPAR-d Product as such exists on the date of termination, to make, have made, import, use, offer for sale and sell such PPAR-d Compound and PPAR-d 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-d Products and PPAR-d Compounds. To the extent that such licenses [*] PPAR-d Products and PPAR-d 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-d Products and/or PPAR-d 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-d Products and PPAR- d

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-d Products and PPAR-d Compounds, and to license any Third Parties to do so.

(d) Trademarks. If Metabolex used with regard to any PPAR-d Product or PPAR-d Compound in a country any trademark, tradename or logo related solely to a PPAR-d Product and/or PPAR-d Compound (**"Metabolex PPAR-d 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-d 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-d Products and PPAR-d 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-d Product or PPAR-d 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-d Products or PPAR-d Compounds.

(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-d Products and/or PPAR-d Compounds or higher than [*] of Metabolex's manufacturing cost for the PPAR-d Products and/or PPAR-d Compounds, all quantities of PPAR-d Products and/or PPAR-d Compounds in the possession of Metabolex or its Affiliates (including, without limitation, clinical trial supplies and PPAR-d Products and/or PPAR-d Compounds intended for commercial sale).

(h) PPAR-d Product/Compound Manufactured by Metabolex. If any PPAR-d Product and/or PPAR-d 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-d Product and/or PPAR-d 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-d Product and/or PPAR-d 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-d Product and/or PPAR-d 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-d Product and/or PPAR-d 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-d Products and/or PPAR-d 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-d Products and/or PPAR-d 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-d Products and/or PPAR-d Compounds and (2) cease conducting any activities with respect to the marketing, promotion, sale or distribution of the PPAR-d Products and/or PPAR-d Compounds.

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

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 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.

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.

(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 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 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 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.

(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]

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-d Compounds
Exhibit C: PPAR-dPatents
Exhibit D: Materials to be Transferred
Exhibit E: Description of [*]
Exhibit F: Replacement Compound Patents

EXHIBIT A

WEIGHTED AVERAGE PERCENTAGE DISCOUNT

(see attached)

[*]

EXHIBIT B

DESCRIPTION OF NUMBERED PPAR-d COMPOUNDS

[*]

EXHIBIT C

PPAR-d PATENTS

[*]

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EXHIBIT D

MATERIALS TO BE TRANSFERRED

[*]

EXHIBIT E

DESCRIPTION OF [*]

[*]

EXHIBIT F

REPLACEMENT COMPOUND PATENTS

[*]

Exhibit 31.1

CERTIFICATIONS

I, Sujal Shah, certify that:

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

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: November 14, 2022

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

Exhibit 31.2

CERTIFICATIONS

I, Daniel Menold, certify that:

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

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: November 14, 2022

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

Exhibit 32.1

CERTIFICATION

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

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2022, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned has set his hand hereto as of November 14, 2022.

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

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

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of CymaBay Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.