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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2014

OR

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

Commission file number: 001-36500

CYMABAY THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**94-3103561**
(State or other jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**

7999 Gateway Blvd., Suite 130
Newark, CA 94560
(510) 293-8800
(Address, including zip code, and telephone number, including area code, of principal executive offices)

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

Title of each class	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	**NASDAQ Capital Market**

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☒

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant based upon the closing price of its Common Stock on the Nasdaq Capital Market on June 30, 2014, was $58,176,723. This excludes 1,114,561 shares of the registrant's Common Stock held by executive officers, directors and stockholders affiliated with directors outstanding at June 30, 2014. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

The number of shares of common stock outstanding as of March 1, 2015, was 15,240,300.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2015 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the registrant's fiscal year ended December 31, 2014, are incorporated by reference in Part III, Items 10-14 of this Annual Report on Form 10-K.

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CYMABAY THERAPEUTICS, INC.
ANNUAL REPORT ON FORM 10-K
For the Year Ended December 31, 2014

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This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expect," "plan," "anticipate," "believe," "estimate," "project," "predict," "potential," "seek," "target," "goals," "intend," and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance, time frames or achievements to be materially different from any future results, performance, time frames or achievements expressed or implied by the forward-looking statements. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K in greater detail under the heading "Risk Factors." Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this filing. You should read this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. We hereby qualify our forward-looking statements by our cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

PART I

Item 1. Business

CymaBay Overview

CymaBay Therapeutics, Inc. is focused on developing therapies to treat metabolic diseases with high unmet medical need, including serious rare and orphan disorders. Arhalofenate, our lead product candidate, is being developed for the treatment of gout. Arhalofenate has successfully completed five Phase 2 clinical trials in patients with gout and consistently demonstrated the ability to reduce gout flares and reduce serum uric acid (sUA). Gout flares are recurring and painful episodes of joint inflammation that are triggered by the presence of monosodium urate crystals that form as a result of elevated sUA levels. We believe the potential for arhalofenate to prevent or reduce flares while also lowering sUA could differentiate it from currently available treatments for gout and classify it as the first potential drug in what we believe could be a new class of gout therapy referred to as Urate Lowering Anti-Flare Therapy (ULAFT). Arhalofenate has established a favorable safety profile in clinical trials involving over 1,000 patients exposed to date. We are currently planning to hold an end of phase 2 meeting with the FDA in the second half of 2015 to review the results of our completed studies and to discuss the design of a phase 3 program for arhalofenate. Our second product candidate, MBX-8025, demonstrated favorable effects on cholesterol, triglycerides and markers of liver health in a Phase 2 clinical trial in patients with mixed dyslipidemia. We are planning to pursue development of MBX-8025 in a number of orphan diseases in which these attributes could be beneficial, such as homozygous familial hypercholestorolemia (HoFH), primary biliary cirrhosis (PBC) and severe hypertriglyceridemia (SHTG). We also believe that MBX-8025 could have utility in the treatment of the more prevalent, but high unmet need, indication of nonalcoholic steatohepatitis (NASH). We plan to initiate one or more pilot or proof-of-concept studies for MBX-8025, beginning with HoFH, in the first half of 2015.

CymaBay has reported net losses of $31.9 million and $10.1 million for the year ended December 31, 2014 and 2013, respectively. Our cash, cash equivalents and marketable securities balances as of December 31, 2014 were $34.8 million. Our average monthly cash usage for the year ended December 31, 2014 was approximately $1.9 million. As more completely described below under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" we have engaged in a series of private placements and public offerings since September 2013, pursuant to which we have raised an aggregate of $56.7 million after deducting

placement agent fees and offering expenses. On November 7, 2014, we filed a $100 million registration statement on Form S-3 with the SEC and also entered into an at-the-market facility (ATM) to sell up to $25 million of common stock under the registration statement, under which, as of March 1, 2015, we have sold shares of common stock with aggregate net proceeds to us of $4.3 million. After giving effect to these financings, we believe that our existing cash will allow us to continue operation through at least the end of 2015.

CymaBay Strategy

Our goal is to become a leading biopharmaceutical company focused on developing and commercializing proprietary new medicines for metabolic and rare diseases with high unmet need. Key elements of our strategy are to:

- develop arhalofenate as a dual-acting treatment to prevent or reduce flares and lower sUA in patients with gout;
- develop MBX-8025 for high unmet need or orphan indications linked to defects in lipid storage, handling and utilization and certain diseases effecting liver function;
- pursue partnerships to advance and commercialize arhalofenate and potentially other clinical candidates; and
- strengthen our patent portfolio and other means of protecting exclusivity.

CymaBay Pipeline Overview

Our pipeline includes three unpartnered clinical stage product candidates and a number of preclinical programs.

Arhalofenate—Gout

Gouty arthritis, or gout, is the most common form of inflammatory arthritis in men and affects more than eight million people in the United States (U.S.). Gout is caused by elevated levels of uric acid in the blood, or hyperuricemia. A great majority, approximately 90%, of gout patients have an under excretion of uric acid. The hallmark symptom of gout is a flare, characterized by debilitating pain, along with tenderness and inflammation of affected joints. Gout has a significant impact on patients' quality of life and health care utilization. Patients experiencing gout flares miss an average of 4.6 more days of work per year than those without gout. Gout flares also result in increased health care utilization with approximately 35% of patients with moderate flare and 50% of patients with severe flare having at least one acute care visit per year.

Gout flares are triggered by the presence of monosodium urate (MSU) crystals in joints. These crystals are formed in tissues when the concentration of sUA exceeds its solubility limit (approximately 6.8 milligrams per deciliter mg/dL). Long term accumulation of MSU crystals in the body leads to the progression of gout with an increase in the frequency of flares, the involvement of multiple joints, their progressive deformation, and the appearance of masses of MSU crystals called tophi. Hence, the goal of treatment is to maintain sUA below 6 mg/dL, or even 5 mg/dL when tophi needs to be dissolved. Elevated levels of sUA, or hyperuricemia, most commonly results from the under excretion of uric acid by the kidney. Uric acid is normally filtered through the glomerular section of the kidney and reabsorbed in the proximal renal tubule back to the blood by specialized urate transporters/exchangers.

Multiple clinical studies indicate that gout patients have a high incidence of comorbidities, such as hypertension (50% or more), chronic kidney disease (~40%), coronary artery disease (>35%), and diabetes (~20%). Managing patients with these comorbidities is challenging because medication currently used to treat gout flares could be contraindicated. For instance, non-steroidal anti-inflammatory drugs (NSAIDs) have renal toxicity and corticosteroids worsen hypertension and diabetes.

Market Opportunity

Unmet Needs in the Treatment of Gout

To halt the progression of gout and provide long term reduction in flares, MSU crystals must be eliminated from the body. Therefore, the major goals of gout treatment are to prevent flares and lower sUA to below 6 mg/dL in order to dissolve MSU crystals. Of the eight million patients with gout in the U.S., we estimate that over three million patients are on urate lowering therapy (ULT) and of these patients on ULTs, as many as 60% may not get to their sUA goal of below 6.0 mg/dL. In addition, we estimate about one million patients continue to experience three or more flares per year. According to a 2012 study, patients having three or more flares per year typically incur $10,000 more in annual health care costs than patients without gout. With a large number of patients not reaching the sUA goal of below 6 mg/dL on current therapies, gout remains a significantly undermanaged disease. Studies have also shown that abrupt decreases in sUA with existing ULTs paradoxically cause an increase in flares, leading many patients to discontinue or avoid therapy. Non-adherence to therapy is thus a significant problem.

Current Treatment

Xanthine oxidase (XO) inhibitors are ULTs that decrease the production of uric acid. The XO inhibitors, allopurinol and febuxostat (marketed by Takeda Pharmaceutical Company Limited as Uloric®), are the most commonly prescribed drugs in the ULT market. Generic allopurinol at doses up to 300 mg accounts for about 90% of ULT prescriptions in the U.S. Studies have shown that the most commonly prescribed doses of these drugs (allopurinol 300 mg or febuxostat 40 mg) in the U.S. result in only about 40% of patients reaching the sUA goal of below 6.0 mg/dL. In addition, both allopurinol and febuxostat can cause an increase in gout flares for up to 6 – 12 months following initiation of treatment.

Uricosurics are ULTs that lowers sUA by promoting the excretion of uric acid by the kidney. Lesinurad (under development by AstraZeneca PLC) is a uricosuric that blocks URAT1, the main urate transporter/exchanger in renal proximal tubules. AstraZeneca PLC announced Phase 3 results for lesinurad in 2013 and 2014. While AstraZeneca announced renal-related adverse events, including kidney stones, for patients taking lesinurad the company has indicated it was proceeding with preparation of regulatory submissions for lesinurad 200 mg combination therapy and has very recently filed a dossier in Europe.

To address the increase in flare rate associated with initiation of ULT therapy, anti-inflammatory drugs such as colchicine and NSAIDs are co-prescribed with ULTs. These agents cause adverse effects. The risks associated with colchicine include diarrhea, nausea, vomiting, and neuromuscular toxicity. Colchicine might also produce myelosuppression and multiple drug interactions, which are reasons why its long term use should be carefully monitored. NSAIDs are associated with gastrointestinal (GI) bleeding that can be severe and life-threatening. Their long-term use is associated with an increased risk of renal toxicity, chronic renal insufficiency and increased cardiovascular morbidity. Steroids are also associated with GI bleedings. They can severely worsen hypertension and diabetes that are frequent comorbities of gout patients and their chronic use is associated with debilitating osteoporosis and bone fractures.

Arhalofenate Addresses the Unmet Needs in Gout

We believe that a significant opportunity exists for arhalofenate as a result of its combined anti-flare activity and its sUA lowering activity. As a Urate Lowering Anti-Flare Therapy (ULAFT), arhalofenate has the potential to address the unmet needs of gout patients by preventing flares while helping patients to achieve sUA target goals. This dual activity might also be advantageous when combining arhalofenate with a XO inhibitors both to increase the number of patients reaching their desired sUA targets and limit the number of flares.

Clinical Studies with Arhalofenate

The Gout Development Program

Arhalofenate is a prodrug which upon absorption is converted to its active form, arhalofenate acid. Arhalofenate acid's dual actions are to inhibit uric acid reabsorption by urate transporters in the kidney and to block the MSU crystal-stimulated production of IL-1ß by macrophages (white blood cells that play an important role in the body's defense against pathogens and foreign matter) in inflamed joints.

Arhalofenate has been studied in five Phase 2 gout clinical studies . The results of these studies collectively support further development of arhalofenate as a potentially safe and effective urate-lowering anti-flare therapy (ULAFT) for the large number of gout patients that are inadequate responders or are intolerant to XO inhibitors. A summary of these five studies is described below:

- Phase 2 Arhalofenate / Febuxostat Combination Study: This study was an open label, single center trial with two cohorts of gout patients (n = 16 each) conducted with the purpose of evaluating the pharmacodynamics, pharmacokinetics and safety of arhalofenate in combination with febuxostat. One cohort received arhalofenate 600 mg once daily for 2 weeks followed by sequential one week periods of co-administration of febuxostat 80 mg and 40 mg. During the final two weeks, febuxostat 40 mg alone was continued. The second cohort received arhalofenate 800 mg for 2 weeks, followed by sequential one week periods of co-administration of febuxostat 40 mg and 80 mg. During the final two weeks, febuxostat 80 mg alone was continued. Patients in both cohorts received flare prophylaxis with colchicines throughout the study. Baseline mean sUA for patients in cohort 1 and 2 were 9.4 and 9.2 mg/dL, respectively. The responder rates (percentages of subjects reaching different sUA targets) are shown below:

Responder rate (%)	sUA mg/dL					
	<6		<5		<4	
Arhalofenate (mg)	FBX 40 mg	FBX 80 mg	FBX 40 mg	FBX 80 mg	FBX 40 mg	FBX 80 mg
0	47	93	7	71	0	29
600	79	94	43*[a]	88	7	31
800	100**[a]	100	93***[a]	93	20	79*[b]

*p < .05 ** p <.01 *** p < .001 [a] vs. 40 mg [b] vs. 80 mg febuxostat

Treatment with arhalofenate 800 mg monotherapy gradually decreased sUA with approximately half of the decrease by day 7. Intraday variations in sUA were <10%. In this study, the combination of febuxostat with arhalofenate was well tolerated, appeared safe and was more efficacious in decreasing sUA than febuxostat alone. With the arhalofenate 800 mg combinations, 100% of subjects achieved sUA <6 mg/dL and 93% <5 mg/dL, which are recommended treatment goals. The combination of arhalofenate 800 mg and febuxostat 80 mg resulted in 79% of subjects achieving <4 mg/dL, a more ambitious goal for patients with high urate crystal burden. On arhalofenate alone, sUA slowly decreased over 2 weeks with small intraday variations in both sUA and fractional excretion of uric acid (FEUA). Low FEUA, a hallmark of gout, was restored toward normal levels. **Conclusion**: This study demonstrated the potent sUA lowering activity of arhalofenate when combined with febuxostat. The arhalofenate 800 mg/feboxustat 40 mg combination could potentially bring most patients to a sUA goal of <6 mg/dL and the arhalofenate 800 mg/febuxostat 80 mg could potentially bring most patients to a sUA goal of <5 mg/dL or, even, less than 4 mg/dL. These lower and more ambitious goals might be particularly beneficial for patients with tophi who have a higher burden of MSU crystals. The combination was well tolerated and appeared safe. The pharmacodynamic properties of aralofenate 800 mg on the kidney, such as the small intra-day variation in FEUA, suggest that the drug should be well tolerated.

- Phase 2b Arhalofenate Gout Flare Study: This study was a randomized, double-blind, placebo- and active-controlled phase 2b trial involving gout patients that experienced at least three flares during the previous year. The study objectives were to evaluate the efficacy and safety of arhalofenate for preventing flares and reducing serum uric acid in gout patients. The primary objective was to evaluate the anti-flare activity of arhalofenate in gout patients in the absence of background colchicine

treatment. A total of 239 subjects were dosed once daily for 12 weeks and were randomized 1:2:2:2:2 to placebo, arhalofenate 600 mg, arhalofenate 800 mg, allopurinol 300 mg and allopurinol 300 mg combined with colchicine 0.6 mg. The primary outcome of efficacy comparing flare rates between the arhalofenate 800 mg to allopurinol 300 mg groups was met with a 46% improvement (p = .0056). Additional key efficacy and safety parameters are presented in the table:

		Placebo	Arhalofenate 600 mg	Arhalofenate 800 mg	Allopurinol 300 mg	Allopurinol 300mg + 0.6 mg COL
	N	28	53	51	54	53
Flare rate		**1.13**	**1.04**	**0.66[a]**	**1.24**	**0.40**
Mean % change	**Week 8**	**+1**	**-14**	**-20**	**-30**	**-24**
in sUA from baseline to	**Week 12**	**-1**	**-12[b]**	**-16[b]**	**-29**	**-25**
Discontinued for safety		**1**	**1**	**1**	**3**	**5**
Serious Adverse Events (SAEs)		**0**	**0**	**1**	**3**	**1**

[a] 46% reduction vs. allopurinol 300 mg (p = .0056) and 41% reduction vs. placebo (p= .049)

[b] p ≤ .001 vs.placebo

There were no SAEs deemed related to arhalofenate. There was one SAE of a documented kidney stone in a patient on allopurinol 300 mg. There were no meaningful differences in the number of patients reporting Treatment Emergent AEs (TEAEs). The most frequent TEAEs were increases in creatine phosphokinase (4.6%), upper respiratory tract infections (3.8%), hypertension and headache (both 3.3%) with no relevant differences between groups. There were no subjects on arhalofenate who developed an abnormal serum creatinine value that was more than 1.5 times above pre-treatment values. Arhalofenate at 800 mg significantly decreased gout flares when compared to allopurinol 300 mg. There was no statistical difference in flare rates between arhalofenate 800 mg and allopurinol 300 mg combined with colchicine. Arhalofenate 800 mg also significantly decreased the flare rate when compared to placebo. Taken together, these results indicate that arhalofenate has anti-inflammatory activities associated clinically with improvement in gout flares. Arhalofenate sUA lowering activity, while significant compared to placebo, was lower than in the allopurinol 300 mg groups. **Conclusion**: This study demonstrated the anti-flare activity of arhalofenate 800 mg when used in the absence of a flare prophylaxis with colchicine. This activity may bring a significant medical benefit to gout patients. Arhalofenate was well tolerated and appeared safe.

- Phase 2a Arhalofenate Monotherapy Study: The monotherapy study was a randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of arhalofenate for the treatment of hyperuricemia in patients with gout. Arhalofenate was given daily at doses of 400 mg and 600 mg for four weeks. A total of 64 patients completed the treatment phase: 22 received placebo, 20 received arhalofenate 400 mg, and 22 received arhalofenate 600 mg. All randomized patients also received colchicine 0.6 mg daily as flare prophylaxis, a preventive treatment for flares. After 4 weeks of treatment, the mean sUA percent (and absolute) changes from Day 1 were: +4% (+0.2 mg/dL) in the placebo group, -15% (-1.4 mg/dL) in the 400 mg arhalofenate group and -23% (-2.3 mg/dL) in the 600 mg arhalofenate group. When compared to placebo, the sUA reductions in both arhalofenate treatment groups were statistically significant (p≤0.0002). Compared to placebo, patients treated with arhalofenate demonstrated dose-dependent reductions in gout flare and sUA. The proportion of patients reporting at least one flare during the treatment phase was 23% (5 of 22), 20% (4 of 20), and 5% (1 of 22) in the placebo, 400 mg, and 600 mg groups, respectively. In addition to flare frequency, both severity and duration of flare were lower in arhalofenate-treated patients. **Conclusion**: This study demonstrated sUA lowering activity of arhalofenate in gout patients. It also suggested that arhalofenate could have anti-flare activity in the clinic, supporting the pre-clinical experiments demonstrating arhalofenate anti-inflammatory activity.
- Phase 2a Arhalofenate / Febuxostat Combination Study: In the febuxostat combination study, arhalofenate up to 600 mg daily was added to febuxostat 80 mg in an open-label, in-patient study to

determine the efficacy, safety, and tolerability of arhalofenate in combination with 80 mg febuxostat once daily. A total of 11 patients were dosed with 80 mg febuxostat during Week 1, 80 mg febuxostat plus 400 mg arhalofenate during Weeks 2-3 and 80 mg febuxostat plus 600 mg arhalofenate during Weeks 4-5. All patients also received 0.6 mg colchicine daily as prophylaxis for gout flare. Mean sUA reductions were -48% at Day 8 (febuxostat 80 mg), -54% at Day 22 (febuxostat 80 mg plus arhalofenate 400 mg), and -60% at Day 36 (febuxostat 80 mg plus arhalofenate 600 mg). Febuxostat 80 mg alone resulted in 100% of patients having sUA less than 6.0 mg/dL, approximately 50% less than 5.0 mg/dL and approximately 10% less than 4.0 mg/dL. The combination of febuxostat 80 mg with arhalofenate 600 mg resulted in 100% of patients below 5.0 mg/dL, approximately 60% below 4.0 mg/dL and almost 20% below 3.0 mg/dL. The proportion of these patients reporting at least one flare was 18% (2 of 11 patients) during Week 1 (febuxostat 80 mg) and 18% (2 of 11 patients) during Weeks 2-3 (febuxostat 80 mg plus arhalofenate 400 mg), respectively. No patient reported the initiation of a flare during Weeks 4-5 (febuxostat 80 mg plus arhalofenate 600 mg). The proportion of patients reporting at least one flare in the two-week follow-up period was 27% (3 of 11 patients). **Conclusion**: This study demonstrated the potent sUA lowering activity of arhalofenate when used in combination with febuxostat. The combination was well-tolerated and appeared safe. The antiflare activity was also suggested.

- Phase 2a Arhalofenate / Allopurinol Combination Study: This study was a randomized, double-blind, placebo-controlled clinical trial designed to evaluate the efficacy, safety and tolerability of arhalofenate 400 mg and 600 mg when given in combination with allopurinol 300 mg and also to evaluate the effect of arhalofenate on the pharmacokinetics (PK, drug levels in the blood) of allopurinol and oxypurinol, (the product of metabolism or active metabolite of allopurinol) that forms in the body after ingestion of allopurinol. Arhalofenate (or placebo) was given once daily at doses of 400 mg and 600 mg, in addition to allopurinol 300 mg, for four weeks to patients who had failed to reach the sUA target of <6 mg/dL with allopurinol 300 mg. All randomized patients also received colchicine 0.6 mg daily as flare prophylaxis. There was no statistically significant difference in sUA reduction in the arhalofenate plus allopurinol groups compared to the allopurinol only group. In the per protocol population, the proportion of patients who reached a sUA target of <6 mg/dL at the end of the treatment phase was 35.5%, 52.9%, and 43.3% in the allopurinol plus placebo group, the allopurinol plus 400 mg arhalofenate group, and the allopurinol plus 600 mg arhalofenate group, respectively. The modest additional sUA reduction observed in the arhalofenate plus allopurinol groups in this study is attributable to an interaction in which arhalofenate reduces the concentration of oxypurinol, the active metabolite of allopurinol. Specifically, arhalofenate promotes the excretion of uric acid as well as oxypurinol given both are typically reabsorbed into the blood stream through the same renal transporters arhalofenate is responsible for blocking. A reduction in gout flares was observed in the arhalofenate 600 mg plus allopurinol group compared to the allopurinol only group. The proportion of patients in a pre-specified per protocol population reporting at least one flare during the 4-week treatment phase was 13% (4 of 31) in the allopurinol 300 mg only group, 18% (6 of 34) in the allopurinol 300 mg plus arhalofenate 400 mg group, and 7% (2 of 30) in the allopurinol 300 mg plus arhalofenate 600 mg group. The mean duration of flares was longer in the allopurinol plus placebo group (6.5 days) than in either the allopurinol plus 400 mg arhalofenate group (2.6 days) or the allopurinol plus 600 mg arhalofenate group (3.5 days). **Conclusion**: This study suggested a limited additional reduction of sUA when adding arhalofenate to allopurinol. This was potentially explained by a reduction in oxypurinol, the active metabolites. It confirmed that febuxostat is the XO inhibitor of choice when combined with arhalofenate. The study again suggested an anti-flare activity of arhalofenate.

Conclusions of Arhalofenate's Clinical Experience

Arhalofenate has been studied in a total of 17 clinical studies with over one thousand subjects both in a type 2 diabetes population and in a gout population. These include Phase 1 studies of safety, tolerability and PK, Phase 2 studies of blood glucose effects in diabetics, and Phase 2 studies of sUA and flare effects in gout patients. Arhalofenate was generally well tolerated and appeared safe.

In the treatment of over two hundred patients with hyperuricemia and a diagnosis of gout, arhalofenate was safe and well tolerated . Arhalofenate produced reduction in sUA whether administered alone or in combination with febuxostat. As a uricosuric, arhalofenate decreases sUA by increasing the urinary excretion of uric acid. Arhalofenate increases the fractional excretion of uric acid and brings it to near normal level without overcorrection.

In addition, arhalofenate has demonstrated that, at 800 mg daily, it decreases the incidence of flares in the absence of background colchicine treatment. This property should bring a medical benefit to gout patients by addressing their most burdensome symptoms. This arhalofenate anti-flare activity should be beneficial when the drug is used as a combination therapy with febuxostat or as a monotherapy in patients who are resistant or have a contra-indication to XO-inhibitors.

Phase 3 Gout Program

The details (design, size, duration, etc.) of the Phase 3 program will be the subject of discussion at an End-of-Phase 2 meeting with the FDA that we plan to request for the second half of 2015. Based on our clinical study results in gout patients to date, we believe arhalofenate in combination with febuxostat 40 mg may result in a majority of patients getting to the medically relevant sUA goal of less than 6.0 mg/dL. With up to 60% of gout patients inadequately responding to allopurinol 300 mg (failing to get sUA below 6.0 mg/dL), we believe a significant opportunity exists for this indication. We also believe that the combination of arhalofenate with febuxostat 80 mg could bring the majority of patients with tophi to their recommended, and more ambitious, goal of less than 5.0 mg/dL. In addition to combination therapy, we believe an indication for arhalofenate as a monotherapy may be relevant for XO intolerant patients or those that are moderately hyperuricemic.

The Phase 3 clinical program is currently planned to include pivotal studies for three patient populations:

(1) Patients with chronic gout having hyperuricemia and who are at risk for flares and who have not achieved their goal of less than 6.0 mg/dL on XO inhibitors;

(2) Patients with tophaceous gout, who in addition to hyperuricemia and risk for flares, also have tophi and often have chronic gouty arthropathy (persistent inflammation in joints with associated tissue damage) and who would benefit from having their sUA less than 5.0 mg/dL; and

(3) Patients who are intolerant to or otherwise cannot take XO inhibitors, for whom there ULT options are limited.

The first two populations will be addressed by arhalofenate 800 mg in combination with febuxostat, and the third would examine arhalofenate 800 mg as a monotherapy. The goal of this program would be to establish clinically meaningful benefit on endpoints for flare parameters and sUA responder rates and changes. Studies in this program will be randomized, double-blind studies, with appropriate controls and statistical power. A small number of Phase 1 studies, including necessary drug-drug interaction studies, or special population studies, will also be conducted prior to submission of an NDA.

MBX-8025

MBX-8025 is a selective agonist for the peroxisome proliferator-activated receptor delta (PPARδ). An agonist is a substance that elicits a response by binding to a receptor. The PPARδ receptor is a nuclear receptor that regulates genes involved in lipid storage, transport and metabolism (particularly fatty acid oxidation) and in insulin signaling and sensitivity. MBX-8025 has the potential to treat a variety of disorders of lipid metabolism and certain diseases of the liver. Previously, MBX-8025 had been in development for the treatment of mixed dyslipidemia, which is characterized by elevated LDL-C and triglycerides (TGs). Results from our Phase 2 clinical study of MBX-8025 in patients with mixed dyslipidemia established effects of the drug that we believe have the potential to benefit patients affected with other conditions. In this study, MBX-8025 demonstrated an anti-atherogenic profile in which it lowered LDL-C, decreased the more atherogenic small dense LDL-C particles and raised HDL-C. In addition, MBX-8025 decreased TGs and free fatty acids. MBX-8025 also decreased C-reactive protein, a marker of systemic and local inflammation. Treatment with MBX-8025 also resulted in

significant reductions in alkaline phosphatase (AP) and in gamma-glutamyl transferase (GGT). Taken together these metabolic improvement suggests that MBX-8025 can address disorders manifested by increases in LDL-C, increases in TGs, liver cholestasis and liver fat accumulation with subsequent inflammation.

Based on an evaluation of possible indications, we have decided to focus the development of MBX-8025 for serious rare and orphan diseases or more prevalent diseases with high unmet medical need and for which we can obtain positive initial clinical data in studies of less than six months duration. Compounds like MBX-8025 that work by interacting with the PPAR class of receptors (PPARa, PPARg and PPARd) are subject to a FDA partial clinical hold which limits clinical studies to durations of less than six months until the two-year rodent carcinogenicity studies are completed and evaluated. The decision as to whether to lift the hold is a benefit/risk assessment made by the FDA in which they weigh the potential benefit of the therapy for the proposed indication vs. any potential risk that may be identified from the rodent carcinogenicity findings. Thus, the lifting of the hold is typically taken when the carcinogenicity data (and the results of any subsequent de-risking experiments) and clinical efficacy data are both in hand. We have completed the carcinogenicity studies for MBX-8025 and have had discussions with the FDA regarding them. We have initiated additional experiments seeking to confirm that the findings have no relevance to humans. Some of these experiments have been completed and others are on-going. Our goal is to complete the outstanding de-risking studies by the time that we have clinical benefit data from the new indications. At that time, the data will be available to enable the FDA to decide whether to lift the clinical hold. We believe that our selected indications are ones for which the risk/benefit assessment of the carcinogenicity findings would be favorable to the patient. We plan to meet with the FDA to discuss lifting the partial clinical hold when additional study results are available.

We believe MBX-8025 may provide a significant benefit for patients across a wide range of rare diseases associated with disorders of lipid metabolism, such as homozygous familial hypercholesterolemia (HoFH) and severe hypertriglyceridemia (SHTG) syndromes, and disorders of liver function, such as primary biliary cirrhosis (PBC). We also believe that MBX-8025 could have utility in the treatment of the more prevalent, but high unmet need, indication of nonalcoholic steatohepatitis (NASH).

Nonclinical Overview

In *in vitro* studies with cells and animal tissues, MBX-8025 was shown to up-regulate genes involved in the metabolism and handling of lipids, most notably stimulation of fatty acid transport and oxidation.

In preclinical studies in rodents, dogs and primates, MBX-8025 demonstrated a variety of beneficial effects on the lipid profile and other metabolic parameters. MBX-8025 treatment increased peripheral oxidation of fatty acids leading to reduced levels of TGs and LDL-C, while raising HDL-C. MBX-8025 also inhibited fat mass accumulation, resulting in attenuation of body weight gain in rodent models of obesity.

Three-month toxicology studies in rodents (alone and in combination with atorvastatin, the generic name of the cholesterol lowering drug Lipitor®) and in monkeys have been completed. In 2014, we initiated six month and twelve month toxicology studies of MBX-8025 in rodents and monkeys, respectively, that we expect to be completed by the first quarter of 2016. In addition, the two-year carcinogenicity studies in mice and rats have been completed. Johnson & Johnson Pharmaceutical Research & Development filed an IND for this compound with the FDA in July 2005 and subsequently transferred the application to CymaBay in March 2007.

Clinical Studies with MBX-8025

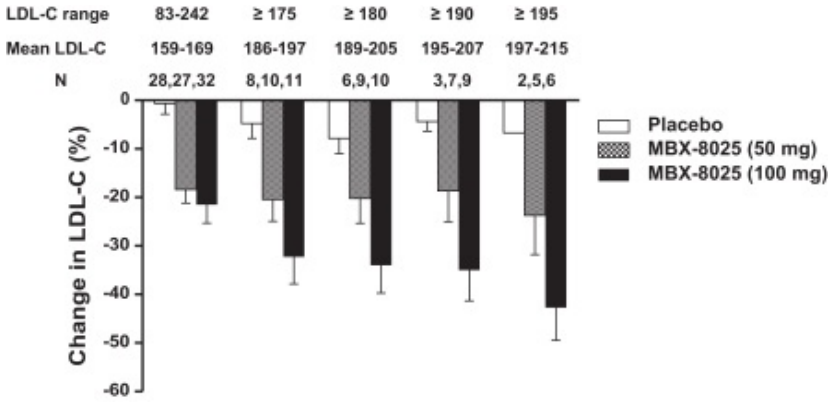
Five Phase 1 and one Phase 2 clinical trials with MBX-8025 have been completed. The phase 2 clinical trial was an eight-week, Phase 2 trial in which MBX-8025 was administered at doses of 50 or 100 mg/day both alone and in combination with 20 mg/day of atorvastatin in moderately obese patients with mixed dyslipidemia. This study also had a placebo arm and a 20 mg/day atorvastatin only arm.

Treatment with MBX-8025 produced multiple beneficial effects on lipid parameters. There were significant overall reductions in total LDL–C (~20%), a parameter known to be correlated with risk of cardiovascular

disease and death. The onset of the LDL-C lowering was rapid with a maximal effect seen by two weeks of treatment which was stably retained up to the end of the 8 weeks of treatment. LDL-C levels returned to pre-treatment levels within two weeks after treatment was stopped.

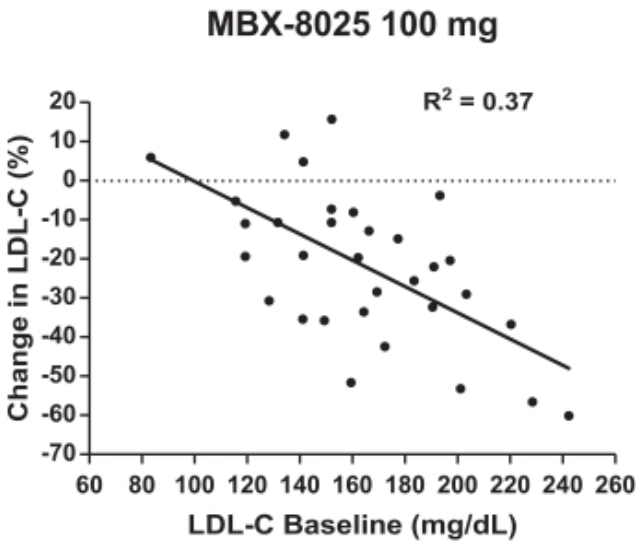
In addition, adding treatment with atorvastatin to MBX-8025 increased the percent change in LDL-C by approximately an additional 20% compared to that of MBX-8025 dosed alone in those patients with baseline LDL-C ≥ 175mg/dL. Decreases in LDL-C were correlated with baseline values, as shown in the figures below. Patients with higher baseline LDL-C values experienced larger reductions in LDL-C. Patients with baseline LDL-C in the 200 mg/dL range had reductions of approximately 40 to 50% with a dose response pattern between the 50 and the 100 mg doses. This suggests that higher doses of MBX-8025 (>100 mg) could potentially produce even larger decreases in LDL-C.

Change in LDL-C (%) according to baseline LDL-C

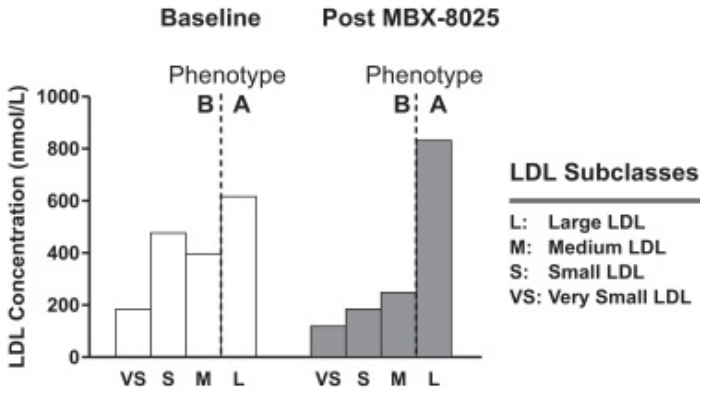


The correlation between baseline LDL-C levels and percentage change in LDL-C for subjects receiving 100 mg MBX-8025 is shown in the graph below and demonstrates a larger effect at higher baseline LDL-C values. These data suggest that MBX-8025 could potentially be a particularly effective treatment for diseases in which LDL-C is markedly elevated.

Individual Patient % Change from Baseline in LDL-C according to Baseline LDL-C



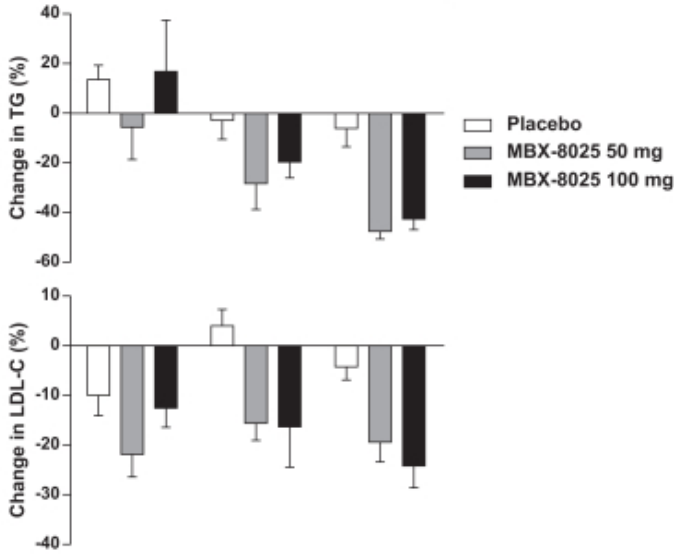
In this trial, lipoprotein particle size measurements were also performed to assess the effect of MBX-8025 on LDL particle subtype distribution. It is believed that small dense LDL particles (type B) are the more atherogenic subtype and that they confer a greater risk for atherogenesis (promotion of arterial plaque formation). As shown below, MBX-8025 selectively depleted the small dense LDL particles, converting them to the larger, more buoyant and less atherogenic phenotype A.



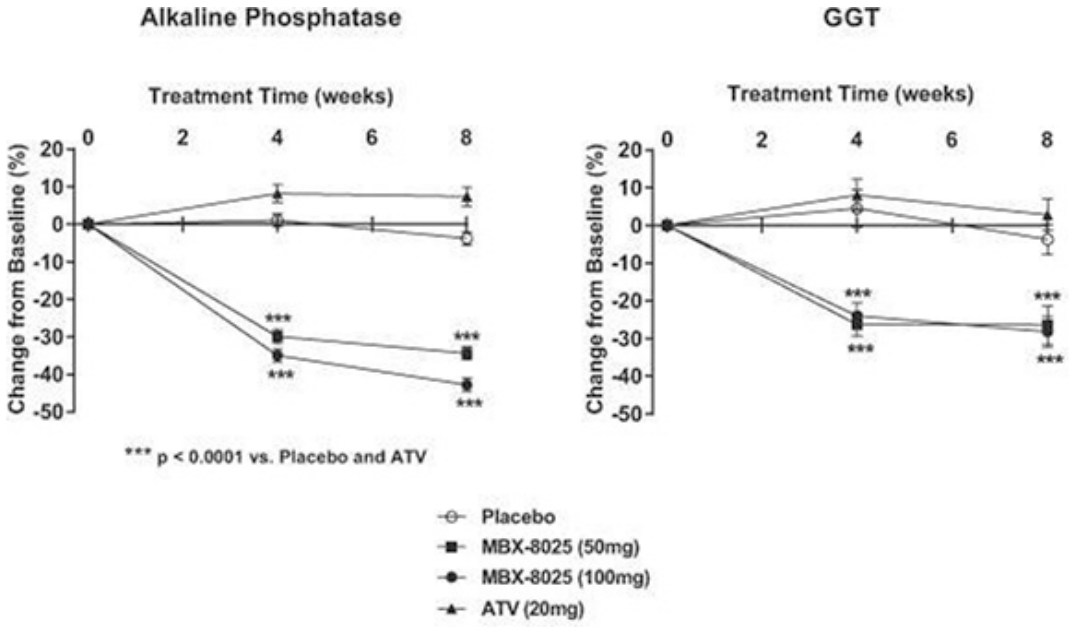
Another beneficial effect of MBX-8025 observed in this Phase 2 clinical trial was a decrease in both TGs (~30%) and free fatty acids (10-15%). The reductions in TGs are illustrated in the figure below where the effect is shown as a function of baseline TG concentration (subdivided into three groups as defined by the National Cholesterol Education Program Adult Treatment Panel III, or NCEP ATP III). At baseline values above 200 mg/dL, the reductions are approximately 50%. Also shown in this figure are the changes in LDL-C for the same patients that experienced the reductions in TGs. At all doses of MBX-8025, the reductions in TGs are associated with a concomitant reduction (15-25%) in LDL-C. Thus, MBX-8025 lowered both TGs and LDL-C in the same patients in this clinical trial. A similar pattern of simultaneous decreases in TGs and LDL-C were observed in the MBX-8025 plus atorvastatin arms of the trial.

Change in TG as a function of baseline TG by NCEP ATP III:

NCEP ATP III	Normal TG	Borderline TG	High TG
TG range	<150	150-199	≥ 200
Mean TG	119-133	171-187	264-295
N	2, 5, 3	10, 7, 6	14, 14, 23



MBX-8025 also produced statistically significant decreases in GGT and AP at both doses of 50 and 100 mg, whereas there were no changes with either placebo or atorvastatin. GGT has been described as a marker of liver inflammation that is associated with the deposition of fat in the liver and AP is a validated marker of liver cholestasis.



Future Development Plan for MBX-8025

We have decided to redirect the development of MBX-8025 toward serious rare and orphan diseases or more prevalent diseases with higher unmet medical need. We have focused on diseases in which there is a clear scientific rationale or clinical data to suggest that the beneficial effects of MBX-8025 observed in our mixed dyslipidemia trial may be retained in that disease population. The indications of interest are HoFH, PBC, SHTG and NASH.

Homozymogous Familial Hypercholesterolemia (HoFH)

HoFH is a rare, life-threatening, genetic disease characterized by marked elevations in plasma levels of LDL-C leading to severe atherosclerosis and the development of premature cardiovascular diseases. While normal LDL-C levels are approximately 100 mg/dL, patients with HoFH may have levels in the 500 to 1000 mg/dL range. Symptomatic cardiovascular disease often presents during the first decades of life leading to myocardial infarction, ischemic stroke, and death. If untreated, most HoFH patients do not survive beyond the age of 30.

HoFH is caused by loss-of-function mutations in both genes of the low-density lipoprotein receptor (LDL-R) protein, leading to reduced or absent LDL-R function. The disease affects approximately one in one million persons. The loss of LDL-R function leads to impaired removal by the liver of LDL-C from the circulation, resulting in exceptionally high LDL-C blood concentrations.

Treatment of HoFH is focused on reducing LDL-C levels, as compelling evidence exists from randomized, double-blind, placebo-controlled studies to support the causality of LDL-C in atherosclerotic cardiovascular disease. Considerable evidence implicates LDL-C as a causal mediator of cardiovascular disease in HoFH patients and reductions in LDL-C can be expected to decrease the risk of cardiovascular disease. It is known that HoFH subjects undergoing LDL-C apheresis, have a reduction in cardiovascular disease events.

Initial treatment of HoFH entails adoption of a low fat diet and exercise program, usually with limited effectiveness. This is followed by conventional pharmacological therapies for reducing LDL-C, including statins, cholesterol absorption inhibitors and bile acid sequestrants. Unfortunately, these conventional therapies work largely through up-regulation of the LDL-R. Thus, they are minimally effective in patients with HoFH in whom LDL-R activity is impaired or absent. Patients having a small amount of residual LDL-R activity may receive a modest reduction in LDL-C with maximal conventional therapy, but most patients with HoFH respond insufficiently.

Plasma apheresis is a selective mechanical filtration of blood that may be used to remove LDL-C and is currently a treatment of last resort for HoFH. Apheresis is a complex and inconvenient procedure that could require an arterio-venous fistula, similar to what is done in chronic dialysis. The procedure is not widely available even in the US. Apheresis reduces LDL-C levels transiently, but must be repeated every one to two weeks because LDL-C levels rebound.

Two new drugs have recently been approved for use in combination with diet, exercise and conventional lipid lowering therapy to treat HoFH. The first is lomitapide (Juxtapid, Aegerion® Pharmaceuticals) that lowers LDL-C by inhibiting microsomal triglyceride transfer protein (MTP), a protein whose activity is required for the production of very low density lipoprotein (VLDL-C), a precursor of LDL-C. Lomitapide produces decreases in LDL-C of approximately 40% from a baseline LDL-C level of 337 mg/dL and gets 28% of patients to the LDL-C target of <100 mg/dL. A side effect of lomitapide treatment is that fat accumulates in the liver, thereby causing hepatic steatosis, with or without concurrent increases in transaminases. For this reason, the drug carries a black box warning and a requirement for monthly liver function monitoring tests. Lomitapide also blocks MTP in enterocytes (cells lining the gastrointestinal tract), leading to an accumulation of fat in the intestinal mucosa. This can reduce the absorption of fat-soluble nutrients and causes gastrointestinal issues (diarrhea, abdominal pain). Subjects on lomitapide should be prescribed concomitant fat-soluble vitamin supplementation and should adhere to a restrictive diet supplying less than 20% of energy from fat.

The second drug is mipomersen (Kynamro, Genzyme Corp.). It lowers LDL-C by acting as an anti-sense oligonucleotide inhibitor that blocks the synthesis of apo B-100, the protein component of LDL-C. Mipomersen lowers LDL-C by approximately 25% from a baseline LDL-C of 439 mg/dL. Like lomitapide, mipomersen causes the accumulation of fat in the liver, confers a risk of hepatic steatosis and carries a black box warning and requirement for monthly liver function monitoring tests.

While these two newly registered drugs offer additional treatment options for patients with HoFH, there remains a high degree of unmet medical need. Even with an aggressive combination of available therapies, subjects with HoFH generally have LDL-C levels substantially above treatment targets. Many patients also have difficulty accessing or tolerating available treatments. We believe that MBX-8025 has attributes that are well suited to the treatment of HoFH and should be independent of the LDL-R activity. MBX-8025 gave durable and significant decreases in LDL-C concentrations of greater than 40% in the Watanabe Heritable Hyperlipidemic rabbit, an accepted pre-clinical model of human HoFH. This is further supported by studies on another PPARδ agonist, GW501516, in mice that lack the LDL-R. Thus, we hypothesize that the LDL-C lowering effect observed in our earlier studies in patients with mixed dyslipidemia may be transferable to patients with HoFH . If MBX-8025 is able to reduce LDL-C in these patients and retains the favorable safety profile observed thus far in our clinical studies, we believe it has the potential to be the front line pharmacological treatment for HoFH. We plan to conduct a small placebo-controlled double-blind proof-of-concept Phase 2 study in patients with HoFH to test this hypothesis.

It is likely that many patients with HoFH will require combination therapy with LDL-C lowering agents in order to achieve enough lowering of LDL-C to reach goal of < 100 mg/dL. Thus we believe there may be opportunities to combine MBX-8025 with other therapies including lomitapide or mipomersen. In this scenario, we note that the ability of MBX-8025 to reduce hepatic fat may potentially mitigate or prevent the development of hepatic steatosis and steato-hepatitis associated with lomitapide and mipomersen.

We are currently planning to initiate a pilot study of MBX-8025 in patients with HoFH in the first half of 2015.

Primary Biliary Cirrhosis (PBC)

PBC is a slowly progressive autoimmune disease of the liver characterized by portal inflammation and immune-mediated destruction of intrahepatic bile ducts. The loss of bile duct function leads to decreased bile secretion and the retention of toxic substances within the liver, resulting in further hepatic damage, fibrosis, cirrhosis and, eventually, liver failure. It is a common cause of liver transplantation.

PBC affects primarily women with peak incidence in the fifth decade of life. It has been recognized as an orphan disease both in the US and in the EU. It is a long-term debilitating and life-threatening disease. Fatigue and pruritus are the most common presenting symptoms. Pruritus (itching), which occurs in 20 to 70% of patients, can be extremely distressing for patients. Other common findings include jaundice, hyperlipidemia (notably hypercholesterolemia), hypothyroidism, osteopenia and osteoporosis, and coexisting autoimmune diseases. Portal hypertension is a late complication of the disease, as is malabsorption, deficiencies of fat-soluble vitamins, and steatorrhea (excess fat in feces).

Currently, the only FDA-approved treatment is ursodeoxycholic acid, also known as ursodiol, an isomer of chenodeoxycholic acid. Ursodiol decreases serum levels of AP, bilirubin, alanine aminotransferase, aspartate aminotransferase, cholesterol, and immunoglobulin M, all of which are elevated in patients with PBC and can serve as biochemical markers of the disease. In a study that combined data from three controlled trials with a total of 548 patients, ursodiol significantly reduced the likelihood of liver transplantation or death after four years. Ursodiol also delayed the progression of hepatic fibrosis in early-stage PBC, but was not effective in advanced disease. It is also known that up to 50% of PBC patients fail to respond to ursodiol therapy.

Other therapies, such as colchicine, methothrexate, prednisone and multiple immunosuppressive regimens have been attempted. However, their efficacy is controversial, limited, or unproven and they are associated with multiple side-effects impacting tolerance and safety. Liver transplantation improves survival in patients with PBC, and it is the only effective treatment for those with liver failure. However cirrhosis recurs in 15% of patients at three years and in 30% at 10 years. As a result, despite the previously mentioned therapeutic interventions, it is recognized that PBC continues to progress in many patients and additional medical treatment is needed to address this disease.

The bile acid analog obeticholic acid (OCA) is in development (Intercept Pharmaceuticals) for PBC. OCA has received orphan designations in US and EU and Fast Track status in the US. Clinical proof-of-concept has been established in two 12-week Phase 2 studies (one in ursodiol non-responders and one in treatment naïve or intolerant patients) using AP as the primary endpoint (<1.67 times the upper limit of normal with >15% reduction) + normal bilirubin. Approximately 40% of patients met the primary endpoint. A Phase 3 study has recently been completed that met its primary endpoint. It remains unclear what the criteria are for registration.

Both AP and GGT are common biochemical markers of cholestasis and their elevation is presumably a consequence of the toxic effects of retention of bile acids in cells in the biliary duct. AP levels in PBC patients have been used as a primary outcome measure in proof-of-concept clinical trials and as a key secondary outcome in pivotal trials. The observation that MBX-8025 produces significant reductions in these surrogate markers suggests that the drug may improve biliary function, ameliorate cholestasis and, hence, be a novel treatment for PBC. The coordinate decrease in AP and GGT levels indicates that the AP decrease is indeed hepatic in origin. The magnitude of the change in AP with MBX-8025 (~40%) is similar to that seen after treatment with ursodeoxycholic acid after eight weeks. In addition to the potential benefit to improving biliary function, we believe MBX-8025 may confer improvements in lipid parameters including reductions in LDL-C and TGs.

The precise mechanism by which MBX-8025 improves cholestasis by acting as a PPARδ agonist is not fully understood. However, there is some supporting preclinical data. In the bile ligation model of cholestasis, the PPARδ agonist KD3010 reduced hepatic injury, fibrosis and inflammation, while increasing survival. In addition, treatment of mice with the PPARδ agonist GW610742 has been shown to produce significant and large increases in bile flow and the production of bile salts.

We are currently evaluating the initiation of a Phase 2 pilot or proof-of-concept study for MBX-8025 in patients with PBC.

Severe Hypertriglyceridemia (SHTG)

Severe HTG (SHTG, TGs > 500 mg/dL) is associated with an increased risk of pancreatitis. As a result, management of HTG and SHTG is also an important goal of lipid therapy. Most patients with HTG can be managed with available TG-lowering therapies including fibrates, niacin and fish oil components. However, there remains an unmet need for addressing SHTG which may arise from a variety of circumstances. It is estimated that there are approximately five million patients in the US with SHTG; however, the Fredrickson classification of hyperlipidemias further subdivides the overall population into several types, some of which can be classified as orphan diseases.

According to the Fredrickson classification of hyperlipidemias, several types of HTG have been identified. This includes Type 1a, a rare genetic disease also called familial chylomicronemia syndrome (FCS), in which chylomicrons are markedly elevated due to decreased activity of liporprotein lipdase (LPL), the enzyme that is primarily responsible for their metabolism. FCS affects about one in one million people worldwide. Type 1b is another form characterized by a deficiency in a protein component of chylomicrons called apo-CII which is needed to activate LPL and facilitate chylomicron metabolism. Another form is Type 5 in which very low density lipoprotein (VLDL) is elevated in addition to chylomicrons and is likely caused by yet incompletely defined variety of molecular defects.

The need for better treatments for SHTG has been recognized and several new therapies either have been brought to the market or are in development. One popular approach has been to develop components of fish oil. Lovaza is a marketed drug that is a mixture of the omega-3 fatty acids esters eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) isolated from fish oil. In patients with SHTG (TGs > 500 mg/dL), it has been shown to reduce TGs by over 40%, but the reductions are accompanied by increases in LDL-C of over 40%. Vascepa, an ethyl ester of EPA, is also on the market for the treatment of SHTG and lowers TGs by approximately 30% with no significant effect on LDL-C. Epanova is a complex mixture of polyunsaturated free fatty acids derived from fish oils, including multiple long-chain omega-3 and omega-6 fatty acids, with EPA, DHA, and docosapentaenoic acid being the most abundant forms. In patients with SHTG, Epanova produced decreases in TGs of approximately 30% with increases of approximately 25% in LDL-C.

Other drugs are currently in earlier stage development for SHTG. ISIS-APOCIIIRX is an oligonucleotide inhibitor of apo-CIII, a lipoprotein component that regulates TG metabolism. Loss-of-function mutations in apo-CIII are associated with lower levels of TGs. In a Phase 2 study in patients with SHTG, ISIS-APOCIIIRX produced reductions in TGs of up to 70%. The effects on LDL-C were not reported. Another product candidate, CAT-2003, produced decreases in both fasting and post prandial (post meal) TGs in normal healthy volunteers and has been advanced into Phase 2 studies in SHTG.

We believe that MBX-8025 may be uniquely able to benefit patients with SHTG by virtue of its ability to simultaneously lower TGs and LDL-C. This benefit has been observed both in monotherapy as well as in combination with atorvastatin in patients with mixed dyslipidemia. Drugs currently marketed for the treatment of SHTG lower TGs with either a worsening or lack of meaningful improvement in LDL-C. Recognizing that SHTG is a heterogeneous collection of diseases, we are continuing our assessment of the best patient populations to study in a small Phase 2 clinical trial.

Non-Alcoholic Fatty Liver Disease (NAFLD) / Nonalcoholic Steatohepatitis (NASH)

NAFLD is a disease characterized by accumulation of fat in the liver of people who drink little or not at all. Approximately one-third of NAFLD patients develop NASH, which is characterized by inflammation in the liver that is often accompanied by fibrosis. This can progress to cirrhosis, followed by eventual liver failure and death. NASH is the third most common reason for liver transplantation in the United States. NASH is a major challenge to healthcare systems worldwide. NASH is initially a silent disease, the first sign of which may be elevations in transaminases such as alanine aminotransferase (ALT) or aspartate aminotransferase (AST) from routine blood test panels. When further evaluation rules out medications, viral hepatitis, alcohol, etc. as a cause, or when imaging studies of the liver show fat, NASH is suspected. A confirmation of a diagnosis of NASH requires a liver biopsy.

There are currently no drugs approved by the FDA for the treatment of NASH. However, a number of clinical studies have been carried out or are underway with drug candidates that may affect disease outcomes in patients with NASH, including OCA (Intercept Pharmaceuticals) and GFT505, a PPARα/δ agonist (Genfit SA).

Based on data from our Phase 2 clinical trial in patients with mixed dyslipidemia and available data from other PPARδ agonists, we believe MBX-8025 may have utility in treating patients with NASH. The decrease in GGT, a biochemical marker which has been recognized to be linked with hepatic fat accumulation, observed in our phase 2 mixed dyslipidemia trial is consistent with results reported for another PPARδ agonist GW501516. A short term clinical trial with GW501516 demonstrated that the compound decreased hepatic fat. In addition to our clinical experience with MBX-8025, along with that of other PPARδ agonists, the well documented property that MBX-8025 induces the oxidation of fatty acid leads us to believe that our compound could potentially benefit patients affected with NAFLD who are further at risk of developing NASH. Although we do not currently anticipate near term development of MBX-8025 in NASH, we continue to evaluate the opportunity among a number of additional indications.

Cymabay Clinical Strategy for MBX-8025

Our initial strategy is to evaluate and carry out pilot or proof-of-concept clinical trials in multiple indications including HoFH, PBC and potentially SHTG to assess whether MBX-8025 is able to produce the predicted improvements in the relevant biomarkers associated with these diseases. In all three indications, clinically and statistically significant markers of disease status can be achieved in relatively small (10-20 patients) studies of three months or less duration. In cases where clinical proof-of-concept is achieved, we believe that we could move rapidly into a Phase 3 registration program based on the high unmet need in these indications. We continue to assess a variety of criteria (patient availability, regulatory pathway clarity, commercial attractiveness, etc.) with which to prioritize these indications. We plan to initiate one or more pilot or proof-of-concept studies for MBX-8025, beginning with HoFH, in the first half of 2015.

MBX-2982

Type 2 diabetes (T2DM) is a chronic debilitating disease characterized by a progressive loss of the normal control of glucose levels in the blood and other tissues. There are several established and emerging classes of drug therapies for diabetes. Over the last decade, injectable drugs have emerged as competing drugs with significant benefits in glucose control as well as effects on weight loss and the potential to protect the pancreas from the damage caused by the progression of diabetes. These drugs are primarily analogs of the natural hormone glucagon-like 1 peptide (GLP-1), and include exenatide, liraglitide and lixisenatide among others. These drugs are given by subcutaneous injection once or twice daily. Their action is to provide glucose-regulated insulin secretion with weight loss and the potential to preserve function of pancreatic islets. New members of this class with once weekly to once monthly dose schedules have been approved or are in late stage development. In spite of the variety of drugs available for the treatment of diabetes, the medications used to manage diabetes have not led to optimal control of hyperglycemia and many are associated with dose-limiting side effects. MBX-2982 is an oral, G-protein coupled receptor (GPR119) agonist being evaluated as a novel therapeutic agent for patients with T2DM, with a dual mechanism including direct effects and indirect effects mediated by gastrointestinal hormones known as incretins on glucose-dependent insulin secretion, as well as potentially beneficial effects on islet health.

GPR119 is expressed in pancreatic islet cells and gastrointestinal hormone secreting cells (enteroendocrine cells). Activation of GPR119 in pancreatic ß-islets either by natural (endogenous) substances or by drugs developed to interact with it (GPR119 agonists) results in direct stimulation of glucose-dependent insulin secretion *in vitro*. Activation of GPR119 in intestinal enteroendocrine cells either by endogenous substances or by GPR119 agonists results in stimulation of glucagon-like peptide 1 (GLP-1) and gastrointestinal inhibitory peptide release, and subsequent enhanced glucose-dependent insulin secretion and suppression of glucagon, leading to improved acute glucose tolerance, both *in vitro* and *in vivo*. MBX-2982 was synthesized and screened as a GPR119 agonist, and is capable of activating endogenous GPR119 in a cell line over-expressing the receptor. MBX-2982 has been shown to increase glucose-dependent insulin secretion in both *in vitro* and in animal models. MBX-2982 also increases incretin hormone levels in animals, which may contribute to its glucose lowering effects.

Nonclinical studies show that MBX-2982 has desirable effects on blood glucose levels, and this effect is additive to the effect of the dipeptidyl peptidase-4 (DPP-4) inhibitor, sitagliptin. Based on these results, there may be an important role for MBX-2982 as a novel therapeutic agent in the treatment of T2DM, alone or in combination with other anti-diabetic agents, including the DPP-4 inhibitors. Presently, there are no other agents approved in the U.S. within this pharmacologic class for the treatment of T2DM.

Extensive preclinical toxicological (up to 6 months in rats and dogs) have been completed, and PK profiling of MBX-2982 has shown low potential for safety risk. We filed an IND for MBX-2982 with the FDA in January 2008.

Clinical Studies with MBX-2982

Four Phase 1 clinical studies and one Phase 2 clinical study with MBX-2982 have been completed and the safety review showed no safety or tolerability concerns with escalating doses (25, 100, and 300 mg/day) tested for up to 4 weeks of dosing. The four-week study in type 2 diabetics can be summarized as follows:

- MBX-2982 generally lowered mean weighted glucose and post-meal glucose during an extended mixed-meal tolerance test (MMTT), although not always to a statistically significant degree and not to the extent of sitagliptin. The effect at the 300 mg dose may have been mitigated by the inclusion of a very small number of patients who experienced extreme worsening of glucose to the degree of being statistical outliers. Decreases in fasting glucose were generally not observed with MBX-2982.
- Four weeks of treatment with MBX-2982 tended to increase insulin, active GLP-1, and total GLP-1 during an extended MMTT. Decreases in glucagon were not as consistently observed. Changes in active GLP-1 were not as robust as those observed with sitagliptin. Four weeks of treatment with MBX-2982 also tended to increase fasting insulin and c-peptide, and decrease fasting triglycerides.
- Overall, the data suggest that MBX-2982 may decrease glucose, potentially through effects on GLP-1, glucagon, and insulin. Changes in HbA1c are difficult to assess over a 4-week treatment period, but trended in the downward direction. Glucose-lowering effects and mechanism of action will need to be explored more robustly in longer duration trials of MBX-2982.
- The PK results observed in this study are similar to those seen in the completed Phase 1 study that used the same formulation, demonstrating dose-dependent increases in drug exposure and a profile supporting once daily oral dosing.
- MBX-2982 at doses of 25, 100, and 300 mg was safe and well tolerated.

Based on these results, we believe further testing with MBX-2982 in combination with sitagliptin and/or metformin for the treatment of diabetes is warranted.

Next Steps in Development of MBX-2982

A proof-of-concept study has been designed to determine the effects of MBX-2982 on fasting and post-challenge blood glucose in patients with T2DM either as dual therapy in combination with either metformin or sitagliptin, or as triple therapy in combination with metformin and sitagliptin.

We do not anticipate conducting this study until a suitable partner is found to contribute funding or resources for the project, or until sometime in the future when we have sufficient capital resources.

License Agreements and Intellectual Property

General

CymaBay actively seeks to obtain, where appropriate, patent protection and regulatory exclusivity for the proprietary technology that it considers important to its business, including compounds, compositions and formulations, their methods of use and processes for their manufacture both in the United States and other countries. CymaBay also relies on trade secrets, know-how, continuing technological innovation and in-licensing to develop and maintain its proprietary position. Our success depends in part on our ability to obtain, maintain and enforce proprietary protection for our product candidates, technology and know–how, to operate without infringing the proprietary rights of others, and to exclude others from infringing our proprietary rights. However, patent protection may not afford CymaBay complete protection against competitors who seek to circumvent CymaBay's patents.

CymaBay also depends upon the skills, knowledge, experience and know-how of its management, research and development personnel, as well as that of its advisors, consultants and other contractors. To help protect its

proprietary know-how, which is not patentable, and for inventions for which patents may be difficult to enforce, CymaBay currently relies and will in the future rely on trade secret protection and confidentiality agreements to protect its interests. To this end, CymaBay requires all of its employees, consultants, advisors and other contractors to enter into confidentiality agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to it of the ideas, developments, discoveries and inventions important to its business.

Collaborations and Licensing Agreements

CymaBay has entered into various arrangements with licensors and licensees. The current collaborations are summarized below.

Johnson and Johnson: In June 2006, CymaBay entered into an exclusive worldwide, royalty-bearing license to MBX-8025 and certain other PPARδ compounds (the "PPARδ Products") with Janssen Pharmaceutical NV, with the right to grant sublicenses to third parties to make, use and sell such PPARδ Products. Under the terms of the agreement, CymaBay has full control and responsibility over the research, development and registration of any PPARδ Products and is required to use diligent efforts to conduct all such activities. Janssen has the sole responsibility for the preparation, filing, prosecution, maintenance of, and defense of the patents with respect to, the PPARδ Products. Janssen has a right of first negotiation under the agreement to license a particular PPARδ Product from CymaBay in the event that CymaBay elects to seek a third party corporate partner for the research, development, promotion, and/or commercialization of such PPARδ Products. Under the terms of the agreement Janssen is entitled to receive up to an 8% royalty on net sales of PPARδ Products. Under the terms of the agreement, if CymaBay does not expend more than a de minimus amount of effort and resources on the research and/or development of at least one PPARδ product, such action would constitute a default under the agreement. In addition, if CymaBay fails to make any payment called for under the agreement, discloses any non-exempt confidential information related to the agreement, or fails to use diligent efforts to promote, market and sell any PPARδ product under the agreement, such action would constitute a default under the agreement. In the event of such default, or upon CymaBay's termination of the agreement, CymaBay shall grant Janssen a worldwide, exclusive, irrevocable license under the agreement in all information that is controlled, developed or acquired by CymaBay which relate to a PPARδ compound or PPARδ product and in all patents that are filed during the term of the agreement with a priority date after the effective date of the agreement and relate to a PPARδ compound or PPARδ product.

In June 2010, CymaBay entered into two development and license agreements with Janssen Pharmaceuticals, Inc. (Janssen) to further develop and discover undisclosed metabolic disease target agonists for the treatment of T2DM and other disorders and received a one-time nonrefundable technology access fee related to the agreements. CymaBay is also eligible to receive up to $228 million in contingent payments if certain development and commercial events are achieved as well as royalties on worldwide net sales of products. No such payments have been made to date. Under the terms of the agreements, Janssen has full control and responsibility over the research, development and registration of any products developed and/or discovered from the metabolic disease targets and is required to use diligent efforts to conduct all such activities. A joint steering committee with equal representation from each party will oversee the development of products. Following June 2012, all decisions of the joint steering committee will be made by Janssen. CymaBay has the sole responsibility, for the preparation, filing, prosecution, maintenance of, and defense of the CymaBay patents with respect to, metabolic disease target agonists. Under the terms of the agreements, if CymaBay discloses any non-exempt confidential information related to the agreements, such action would constitute a default under the agreements. In addition, if CymaBay breaches any of its representations or warranties under the agreements, such action would constitute a default. In the event of a default, the agreements do not provide that CymaBay will lose any of its rights to the intellectual property developed under the agreement.

DiaTex: On June 30, 1998, we entered into a License and Development Agreement with DiaTex, Inc. Under the agreement, DiaTex granted us an exclusive license to develop and commercialize therapeutic products

containing halofenate, its enantiomers (mirror images, including arhalofenate), derivatives, and analogs (the licensed products) for the treatment of diseases. Under terms of the agreement, DiaTex will work cooperatively and assist us in conducting a program for the research and development of halofenate and its enantiomers including the right to sublicense, to use and to practice all patents controlled by DiaTex that claim halofenate and its enantiomers, and all information, data, know-how, trade secrets, inventions, developments, results, techniques and materials, whether or not patentable, that are necessary or useful towards such commercialization. Under the agreement, we are obligated to use diligent efforts to conduct preclinical and clinical testing of halofenate and its enantiomers in order to determine its efficacy for use in the treatment or prevention of human diseases or conditions. On April 15, 1999 the agreement was amended by the parties to allow DiaTex to transfer to us their interest in an IND application that they filed with the FDA. The amendment also provided for DiaTex to indemnify us against any and all losses resulting or arising from any third party claims, actions or proceedings under the IND application, any negligent or wrongful acts or omissions of DiaTex in connection with the IND application, and any misrepresentations by DiaTex relating to the license agreement. Under the amendment, we will provide the same indemnifications to DiaTex with respect to any third party claims, actions, or proceedings in connection with negligent or wrongful conduct of clinical trials relating to the license agreement, provided the claims are not related to negligent or wrongful acts or omissions committed by DiaTex.

The license agreement contains a $2,000 per month license fee as well as a requirement to make additional payments for development achievements and royalty payments on any sales of licensed products. DiaTex is entitled to up to $0.8 million for the future development of arhalofenate, as well as a 2% royalty payment on any net sales of products containing arhalofenate. A $50,000 milestone payment was made in May 2005 but no other milestone or royalty payments have been made since then. The agreement will expire upon the expiration of the last of DiaTex's patents related to the license granted, or, if later, the expiration of all payment obligations under the agreement. The agreement may also terminate upon a material breach by DiaTex or us, if written notice of such breach is delivered to the breaching party, and the breaching party has not (i) cured the breach or (ii) initiated good faith efforts to cure the breach within a specified time period. Under the terms of the agreement, if we fail to use diligent efforts to conduct preclinical and clinical testing of halofenate and its enantiomers to determine its efficacy for use in the treatment or prevention of human diseases or conditions, fail to make any payment called for under the agreement, or disclose non-exempt confidential information under the agreement, such action would constitute a material breach under the agreement. In addition, if we fail to execute all instruments and assignments or fail to take any action to effect joint ownership of any enantiomer patent with DiaTex, such action would constitute a material breach under the agreement. We may terminate the agreement at any time if we determine we are no longer interested in DiaTex's license grant, provided we provide sufficient written notice within a specified time period.

Research and Development Agreements

INC Research: In February 2014, we entered into a Master Services Agreement with INC Research, LLC and related initial work order for INC Research to provide contract clinical research and development services to us in connection with our Phase 2b study. The Agreement provides that we may engage INC Research from time to time to provide services in accordance with work orders mutually agreed and budgeted between the parties for clinical research and development of arhalofenate which total is anticipated to exceed approximately $8 million. The master services agreement provides customary terms and conditions, including those for performance of services by INC Research in compliance with work orders, standard operating procedures, FDA and ICH requirements and all applicable laws. We remain responsible for all regulatory responsibilities and the determination of any work orders, subject to mutual agreement on the specific terms of any such work orders. The master services agreement has a term of five years; provided that we may terminate the master services agreement or any individual work order on thirty (30) days written notice, or immediately in the event of any safety risk associated with the services the being performed. In addition, either party may terminate the master services agreement or any applicable work order upon thirty (30) days written notice for a material breach by the other party.

Intellectual Property

CymaBay owns and co-owns approximately 35 United States patents, 198 foreign patents, as well as 19 United States patent applications and 184 foreign and Patent Cooperation Treaty applications which are counterparts to certain United States patents and patent applications. In addition, we license from third parties approximately 17 United States patents and 1 United States patent application, 255 foreign patents and 65 foreign and Patent Cooperation Treaty applications which are counterparts to certain United States patents and patent applications. These patents and patent applications include claims covering various aspects of our product pipeline and research and development strategies, including: arhalofenate crystal forms, methods of use both alone and in combination with other drugs and methods of manufacture, certain PPAR delta agonists, their compositions and uses, certain GPR119 agonist compositions and uses and undisclosed metabolic disease target agonist compositions and uses.

The arhalofenate portfolio consists of approximately 135 issued patents and 87 pending patent applications relating to composition, method of use or methods of manufacture. We believe our issued patents protect Arhalofenate through at least 2019-2029 before accounting for any potential patent term extension. The MBX-8025 portfolio consists of approximately 273 issued patents and 81 pending patent applications related to composition and method of use that we believe protect it through at least 2024-2026 before accounting for any potential patent term extension. Patent and trade secret protection is critical to our business. Our success will depend in large part on our ability to obtain, maintain, defend and enforce patents and other intellectual property to extend the life of patents covering our product candidates, to preserve trade secrets and proprietary know-how, and to operate without infringing the patents and proprietary rights of third parties we actively seek patent protection in the U.S.

Manufacturing

CymaBay does not currently own or operate manufacturing facilities for the production or testing of arhalofenate or other product candidates that it develops, nor does it have plans to develop its own manufacturing operations in the foreseeable future. CymaBay presently depends on third party contract manufacturers to obtain all of its required raw materials, Active Pharmaceutical Ingredients (APIs) and finished products for its clinical studies for arhalofenate. CymaBay has executed manufacturing agreements for its API and clinical supplies of arhalofenate and MBX-8025 with established manufacturing firms which are responsible for sourcing and obtaining the raw materials necessary for the finished products. The raw materials necessary to manufacture the API for arhalofenate, MBX-8025 and MBX-2982 are available from more than one source and CymaBay has also executed manufacturing agreements for the production of MBX-8025 and MBX-2982.

Siegfried AG

On April 30, 2012, CymaBay entered into a Development and Clinical Manufacture Agreement with Siegfried AG for the manufacturing of the API necessary for the tablet form of arhalofenate. Under the agreement, CymaBay shall deliver or Siegfried shall obtain the raw materials necessary for the API. CymaBay owns the rights, title and interest to the deliverables and intellectual property covering the deliverables generated under the agreement. Siegfried shall grant a non-exclusive license to CymaBay to use Siegfried intellectual property to exploit any product or service based or derived from the deliverables under the agreement. Both Siegfried and CymaBay have agreed to indemnify the other party with respect to losses due to the breach of a covenant or obligation under the agreement or the gross negligence, recklessness or intentional misconduct of the other party. CymaBay may terminate the agreement at any time with written notice and Siegfried may terminate the agreement in the event CymaBay discontinues its activities related to the development or commercialization of the API for arhalofenate. In addition, either party may terminate the agreement at any time for material breach under the agreement or in the case of insolvency of the other party.

Patheon Inc.

On June 5, 2012, CymaBay entered into a Development and Clinical Manufacture Agreement with Patheon Inc. for the manufacturing of the tablet form of arhalofenate. Under the agreement, CymaBay shall deliver the API or Patheon shall obtain the API from a qualified vendor. CymaBay owns the rights, title and interest to the deliverables and intellectual property generated by Patheon in connection with the performance of the services for CymaBay under the agreement. Both Patheon and CymaBay have agreed to indemnify the other party with respect to losses due to the breach of a covenant or obligation under the agreement or the gross negligence, recklessness or intentional misconduct of the other party. CymaBay may terminate the agreement at any time with written notice provided that CymaBay terminates the agreement within certain times in advance of the start date of certain services. In addition, either party may terminate the agreement at any time for material breach under the agreement.

Metrics Inc.

On October 31, 2006, CymaBay entered into a Standard Development Agreement with Metrics, Inc. Under the agreement, Metrics will provide CymaBay with pharmaceutical development, formulation and analytical services in consideration of which CymaBay will provide appropriate compensation as outlined in the agreement. CymaBay owns the rights, title and interest to the intellectual property relating to all pharmaceutical products developed or manufactured for CymaBay by Metrics, as well as any active pharmaceutical ingredient provided to Metrics by CymaBay. CymaBay has agreed to indemnify Metrics against third party claims that involve the breach by CymaBay of any of its obligations, warranties or representations under the agreement, and Metrics has agreed to indemnify CymaBay against third party claims that involve (i) the negligence, gross negligence, or intentional misconduct on the part of Metrics, (ii) a failure by Metrics to comply with the law in their performance of the agreement, or (iii) a breach of Metrics' obligations, covenants, representations, or warranties under the agreement. Either party may terminate the agreement at any time with advance written notice.

Research & Development Costs

Research and development costs for the years ended December 31, 2014 and 2013 were $15.8 million and $4.5 million, respectively.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those CymaBay is developing. The pharmaceutical drug product candidates that CymaBay develops must be approved by the Food and Drug Administration (FDA) before they may be legally marketed in the United States.

United States Pharmaceutical Product Development Process

In the United States, the FDA regulates pharmaceutical products under the Federal Food, Drug and Cosmetic Act, and implementing regulations. Pharmaceutical products are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil

or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on CymaBay. The process required by the FDA before a pharmaceutical product may be marketed in the United States generally involves the following:

- Completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices (GLP) or other applicable regulations;
- Submission to the FDA of an Investigational New Drug application (IND), which must become effective before human clinical studies may begin;
- Performance of adequate and well-controlled human clinical studies according to the FDA's current Good Clinical Practices (GCP), to establish the safety and efficacy of the proposed pharmaceutical product for its intended use;
- Submission to the FDA of a New Drug Application (NDA) for a new pharmaceutical product;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the pharmaceutical product is produced to assess compliance with the FDA's current Good Manufacturing Practice standards (cGMP), to assure that the facilities, methods and controls are adequate to preserve the pharmaceutical product's identity, strength, quality and purity;
- Potential FDA audit of selected preclinical and clinical study sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA.

The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources and approvals are inherently uncertain.

Before testing any compounds with potential therapeutic value in humans, the pharmaceutical product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the pharmaceutical product candidate. These early proof-of-principle studies are done using sound scientific procedures and thorough documentation. The conduct of the single and repeat dose toxicology and toxicokinetic studies in animals must comply with federal regulations and requirements including Good Laboratory Practices. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA has concerns and notifies the sponsor. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin. If resolution cannot be reached within the 30-day review period, either the FDA places the IND on clinical hold or the sponsor withdraws the application. The FDA may also impose clinical holds on a pharmaceutical product candidate at any time before or during clinical studies due to safety concerns or non-compliance. Accordingly, CymaBay cannot be sure that submission of an IND will result in the FDA allowing clinical studies to begin, or that, once begun, issues will not arise that suspend or terminate such clinical study.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and FDA to reach agreement on the next phase of development. Sponsors typically use the End-of-Phase 2 meeting to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical trial that they believe will support approval of the new drug.

Clinical studies involve the administration of the pharmaceutical product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the clinical study sponsor's control. Clinical studies are conducted under protocols detailing, among other things, the

objectives of the clinical study, dosing procedures, subject selection and exclusion criteria, how the results will be analyzed and presented and the parameters to be used to monitor subject safety. Each protocol must be submitted to the FDA as part of the IND. Clinical studies must be conducted in accordance with GCP. Further, each clinical study must be reviewed and approved by an independent institutional review board (IRB) at, or servicing, each institution at which the clinical study will be conducted. An IRB is charged with protecting the welfare and rights of study participants and considers such items as whether the risks to individuals participating in the clinical studies are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical study subject or his or her legal representative and must monitor the clinical study until completed.

Human clinical studies are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The pharmaceutical product is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.
- Phase 2. The pharmaceutical product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases, to determine dosage tolerance, optimal dosage and dosing schedule and to identify patient populations with specific characteristics where the pharmaceutical product may be more effective.
- Phase 3. Clinical studies are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These clinical studies are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. The studies must be well-controlled and usually include a control arm for comparison. One or two Phase 3 studies are required by the FDA for an NDA approval, depending on the disease severity and other available treatment options.
- Post-approval studies, or Phase 4 clinical studies, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication.
- Progress reports detailing the results of the clinical studies must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects. Phase 1, Phase 2 and Phase 3 clinical studies may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend a clinical study at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the pharmaceutical product has been associated with unexpected serious harm to patients.

Concurrent with clinical studies, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the pharmaceutical product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the pharmaceutical product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final pharmaceutical product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the pharmaceutical product candidate does not undergo unacceptable deterioration over its shelf life.

United States Review and Approval Processes

The results of product development, preclinical studies and clinical studies, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the pharmaceutical product, proposed

labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances.

In addition, under the Pediatric Research Equity Act (PREA), an NDA or supplement to an NDA must contain data to assess the safety and effectiveness of the pharmaceutical product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any pharmaceutical product for an indication for which orphan designation has been granted.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act (PDUFA), the FDA has 10 months from filing in which to complete its initial review of a standard NDA and respond to the applicant, and six months from filing for a priority NDA. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs. The review process and the PDUFA goal date may be extended by three months if the FDA requests or if the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

After the NDA submission is accepted for filing, the FDA reviews the NDA application to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA may refer applications for novel pharmaceutical products or pharmaceutical products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the pharmaceutical product approval process, the FDA also will determine whether a risk evaluation and mitigation strategy (REMS) is necessary to assure the safe use of the pharmaceutical product. If the FDA concludes that a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without a REMS, if required.

Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites as well as the site where the pharmaceutical product is manufactured to assure compliance with GCP and cGMP. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. In addition, the FDA will require the review and approval of product labeling.

The NDA review and approval process is lengthy and difficult and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical studies are not always conclusive and the FDA may interpret data differently than CymaBay interprets the same data. The FDA will issue a complete response letter if the agency decides not to approve the NDA. The complete response letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical studies. Additionally, the

complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require Phase 4 testing which involves clinical studies designed to further assess pharmaceutical product safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Post-Approval Requirements

Any pharmaceutical products for which CymaBay receives FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, prohibitions on promoting pharmaceutical products for uses or in patient populations that are not described in the pharmaceutical product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities and promotional activities involving the internet. Failure to comply with FDA requirements can have negative consequences, including adverse publicity, enforcement letters from the FDA, actions by the United States Department of Justice and/or United States Department of Health and Human Services Office of Inspector General, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Although physicians may prescribe legally available pharmaceutical products for off-label uses, manufacturers may not directly or indirectly market or promote such off-label uses.

CymaBay relies, and expects to continue to rely, on third parties for the production of clinical and commercial quantities of CymaBay's products. Manufacturers of CymaBay's products are required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. cGMP regulations require, among other things, quality control and quality assurance, as well as the corresponding maintenance of records and documentation. Pharmaceutical product manufacturers and other entities involved in the manufacture and distribution of approved pharmaceutical products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal of the product from the market. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

The FDA also may require post-marketing testing, known as Phase 4 testing, risk minimization action plans and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product.

U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act, or FCPA, prohibits certain individuals and entities, including CymaBay, from promising, paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, directly or indirectly, to obtain or retain business or an improper advantage. The

U.S. Department of Justice and the U.S. Securities and Exchange Commission, or SEC, have increased their enforcement efforts with respect to the FCPA. Violations of the FCPA may result in large civil and criminal penalties and could result in an adverse effect on a company's reputation, operations, and financial condition. A company may also face collateral consequences such as debarment and the loss of export privileges.

Federal and state fraud and abuse laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain business practices in the biopharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payment, ownership interests and providing anything at less than its fair market value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and CymaBay's practices may not in all cases meet all of the criteria for statutory exemptions or safe harbor protection. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The reach of the Anti-Kickback Statute was also broadened by the Patient Protection and Affordable Health Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the PPACA, which, among other things, amends the intent requirement of the federal Anti-Kickback Statute. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses. Many states also have statutes or regulations similar to the federal Anti-Kickback Statute and False Claims Act, which state laws apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Also, the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new federal criminal statutes that prohibit knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payers and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Because of the breadth of these laws and the narrowness of the federal Anti-Kickback Statute's safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have a material adverse effect on our business, financial condition and results of operations. If CymaBay obtains FDA approval for any of our product candidates and begin commercializing those products in the United States, CymaBay's operations may be

directly, or indirectly through our customers, distributors, or other business partners, subject to various federal and state fraud and abuse laws, including, without limitation, anti-kickback statutes and false claims statutes. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates"—independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

If CymaBay's operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to CymaBay, CymaBay may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, and the curtailment or restructuring of CymaBay's operations, any of which could adversely affect CymaBay's ability to operate its business and CymaBay's results of operations. To the extent that any of CymaBay's product candidates are ultimately sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of the use of CymaBay's pharmaceutical product candidates, some of CymaBay's patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved pharmaceutical product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, CymaBay may intend to apply for restoration of patent term for one of its currently owned or licensed patents to add patent life beyond its current expiration date, depending upon the expected length of the clinical studies and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the U.S. Food, Drug, and Cosmetic Act can also delay the submission or the approval of certain applications of other companies seeking to reference another company's NDA. Currently seven years of reference product exclusivity are available to pharmaceutical products designated as Orphan Drugs, during which the FDA may not approve generic products relying upon the reference product's data. Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric clinical study in accordance with an FDA-issued "Written Request" for such a clinical study.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical product candidates for which CymaBay obtains regulatory approval. In the United States and markets in other countries, sales of any products for which CymaBay receives regulatory approval for commercial sale will depend in part upon the availability of reimbursement from third-party payors. Third-party payors include government payors such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a pharmaceutical product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the pharmaceutical product. Third-party payors may limit coverage to specific pharmaceutical products on an approved list, or formulary, which might not include all of the FDA-approved pharmaceutical products for a particular indication.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. CymaBay may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of its products, in addition to the costs required to obtain the FDA approvals. CymaBay's pharmaceutical product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a pharmaceutical product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable CymaBay to maintain price levels sufficient to realize an appropriate return on CymaBay's investment in product development. In addition, in the United States there is a growing emphasis on comparative effectiveness research, both by private payors and by government agencies. To the extent other drugs or therapies are found to be more effective than CymaBay's products, payors may elect to cover such therapies in lieu of CymaBay's products and/or reimburse CymaBay's products at a lower rate.

In 2003, the United States government enacted legislation providing a partial prescription drug benefit for Medicare recipients, which became effective at the beginning of 2006. Government payment for some of the costs of prescription drugs may increase demand for any products for which CymaBay receives marketing approval. However, to obtain payments under this program, CymaBay would be required to sell products to Medicare recipients through prescription drug plans operating pursuant to this legislation. As part of their participation in the Medicare prescription drug program, these plans negotiate discounted prices for prescription drugs and will likely do so for CymaBay's products. Federal, state and local governments in the United States continue to consider legislation to limit the growth of health care costs, including the cost of prescription drugs. Future legislation and regulations could limit payments for pharmaceuticals such as the drug candidates that CymaBay is developing.

Different pricing and reimbursement schemes exist in other countries. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any pharmaceutical product candidates for which CymaBay receives regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and CymaBay expects this will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which CymaBay receives regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce

healthcare costs. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee.

Government payment for some of the costs of prescription drugs may increase demand for CymaBay's products for which CymaBay receives marketing approval. However, any negotiated prices for CymaBay's products covered by a Part D prescription drug plan will likely be lower than the prices CymaBay might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from Medicare Part D may result in a similar reduction in payments from non-governmental payors.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of any product, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates. If third-party payors do not consider CymaBay's products to be cost-effective compared to other available therapies, they may not cover our products as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow CymaBay to sell its products on a profitable basis.

In March 2010 the PPACA was enacted, which includes measures to significantly change the way healthcare is financed by both governmental and private insurers. Among the provisions of the PPACA of importance to the pharmaceutical and biotechnology industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, that began in 2011;
- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

- new requirements under the federal Open Payments program, created under Section 6002 of the PPACA and its implementing regulations, that manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to the U.S. Department of Health and Human Services, or HHS, information related to "payments or other transfers of value" made or distributed to physicians and teaching hospitals, and that applicable manufacturers and applicable group purchasing organizations report annually to HHS ownership and investment interests held by physicians and their immediate family members, with reporting to the Centers for Medicare & Medicaid Services, or CMS, required by March 31 of each calendar year;
- a requirement to annually report drug samples that manufacturers and distributors provide to physicians, effective April 1, 2012;
- expansion of health care fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- creation of the Independent Payment Advisory Board which, beginning in 2014, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations; and
- establishment of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending that began on January 1, 2011.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. In August 2011, the president signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction, or joint committee, to recommend proposals in spending reductions to Congress. The joint committee did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. In January 2013, the president signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our financial operations.

International Regulation

In addition to regulations in the United States, there are a variety of foreign regulations governing clinical studies and commercial sales and distribution of CymaBay's future product candidates. Whether or not FDA approval is obtained for a product, approval of a product must be obtained by the comparable regulatory authorities of foreign countries before clinical studies or marketing of the product can commence in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical studies, product licensing, pricing and reimbursement vary greatly from country to country. In addition, certain regulatory authorities in select countries may require CymaBay to repeat previously conducted preclinical and/or clinical studies under specific criteria for approval in their respective country which may delay and/or greatly increase the cost of approval in certain markets targeted for approval by CymaBay.

Corporate Information

CymaBay Therapeutics, Inc., formerly Metabolex, Inc., was incorporated under the laws of the State of Delaware on October 5, 1988, originally under the name Transtech Corporation. Our executive offices are located at 7999 Gateway Blvd., Suite 130, Newark, CA 94560. The telephone number at our executive office is (510) 293-8800. Our corporate website address is www.cymabay.com. We do not incorporate the information contained on, or accessible through, our website into this Annual Report on Form 10-K, and you should not consider it part of this Annual Report.

Implications of Being an "Emerging Growth Company"

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an "emerging growth company," we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- reduced disclosure about our executive compensation arrangements;
- no requirement that we solicit non-binding advisory votes on executive compensation or golden parachute arrangements; and
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

CymaBay intends to take advantage of the reduced disclosure obligations. Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. In other words, an emerging growth company can elect to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. CymaBay has elected to avail itself of this exemption to take advantage of the extended transition period for complying with new or revised accounting standards.

CymaBay could remain an emerging growth company for up to five years, or until the earliest of (i) the last day of the first fiscal year in which CymaBay's annual gross revenues exceed $1 billion, (ii) the date that CymaBay becomes a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of CymaBay's common stock that are held by non-affiliates exceeds $700 million as of the last business day of CymaBay's most recently completed second fiscal quarter, (iii) the date on which CymaBay has issued more than $1 billion in non-convertible debt during the preceding three-year period and (iv) the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act. At this time CymaBay expects to remain an "emerging growth company" for the foreseeable future.

CymaBay also qualifies as a "smaller reporting company" and thus has the advantage of not being required to provide the same level of disclosure as larger public companies.

Employees

As of March 1, 2015, CymaBay had 18 full-time employees, 6 of whom hold Ph.D.s and 3 of whom hold a Masters degree in relevant areas of expertise.

Executive Officers of Registrant

As of March 1, 2015, our executive officers, who are appointed by and serve at the discretion of the board of directors, were as follows:

Name	Age	Position Held With CymaBay
Executive Officers		
Harold Van Wart, Ph.D.	67	President, Chief Executive Officer & Director
Sujal Shah	41	Chief Financial Officer
Charles A. McWherter, Ph.D.	58	Senior Vice President, Chief Scientific Officer
Pol Boudes, M.D.	57	Chief Medical Officer

Biographical Information

Executive Officers

Harold E. Van Wart, Ph.D. has served as CymaBay's President since April 2001 and Chief Executive Officer and member of its board of directors since 2003. He served as Chief Operating Officer from December 2002 to January 2003 and Senior Vice President, Research and Development from October 2000 to December 2002. From 1999 to 2000, Dr. Van Wart was vice president and therapy area head for arthritis and fibrotic diseases at Roche Biosciences, a biopharmaceutical company. From 1992 to 1999, he was vice president and director of the institute of biochemistry and cell biology at Syntex Corporation, a biopharmaceutical company acquired by Roche Biosciences in 1994. From 1978 to 1992, Dr. Van Wart served on the faculty of Florida State University. Dr. Van Wart holds a Ph.D. from Cornell University and a B.A. from SUNY Binghamton. Dr. Van Wart has been a member of the board of directors of Conatus Pharmaceuticals since 2007. He currently also serves on the Emerging Companies and Health Section Governing Boards of the Biotechnology Industry Organization (BIO), as well as on its board of directors, and on the board of directors and executive committee at BayBio.

Sujal Shah joined CymaBay as Chief Financial Officer in December of 2013. Prior to that he served as a consultant and acting Chief Financial Officer since June 2012. From 2010 to 2012, Mr. Shah served as Director, Health Care Investment Banking for Citigroup Inc., where he was responsible for managing client relationships and executing strategic and financing related transactions for clients focused in life sciences. From 2004 to 2010 Mr. Shah was employed with Credit-Suisse, last serving in the capacity as Vice President, Health Care Investment Banking Group. Mr. Shah received a MBA from Carnegie Mellon University – Tepper School of Business in 2004 and a M.S. from Northwestern University in Biomedical Engineering in 1997.

Charles A. McWherter, Ph.D. has served as our Senior Vice President and Chief Scientific Officer since July 2007. From 2003 to 2007, he served as Vice President and head of the cardiovascular therapeutics areas of Pfizer Inc., a biopharmaceutical company. From 2001 to 2003, Dr. McWherter served as Vice President of Drug Discovery at Sugen, Inc., a biopharmaceutical company acquired by Pfizer Inc. in 2003. Dr. McWherter obtained his Ph.D. from Cornell University.

Pol Boudes, M.D. joined CymaBay in April 2014 as our Chief Medical Officer. Prior to joining CymaBay, Dr. Boudes was Chief Medical Officer at Amicus Therapeutics, where he was responsible for clinical development, medical affairs and quality assurance and toxicology. From 2004 to 2009, Dr. Boudes was with Berlex Laboratories (which merged with Bayer HealthCare Pharmaceuticals in 2006) where he held the position of Vice President, Global Clinical Development, Women's, Health Care US. From 1990 to 2004, he held positions of increasing responsibility with Wyeth-Ayerst Research both in Philadelphia, PA and in Europe, with Hoffmann-La Roche, and with Pasteur-Merieux Serums & Vaccines. Dr. Boudes received his M.D. from the University of Aix-Marseilles, France. He completed his internship and residency in Marseilles and in Paris, France and was an Assistant Professor of Medicine at the University of Paris. He is specialized in Endocrinology and Metabolic Diseases, Internal Medicine, and Geriatric diseases.

Item 1A. Risk Factors

Risks Related to Our Financial Condition and Capital Requirements

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

We have consumed substantial amounts of capital to date as we continue our research and development activities, including our Phase 2b study of arhalofenate. As of December 31, 2014, we had cash, cash equivalents and marketable securities of approximately $34.8 million. In addition, in January and February 2015, we obtained $4.3 million in net proceeds received from the sale of our common stock under an at-the-market facility. We believe that our existing cash will allow us to continue operation through at least the end of 2015. We currently believe that we will need to raise additional capital to continue our operations beyond 2015. Our monthly spending levels vary based on new and ongoing development and corporate activities.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete. We expect our research and development expenses to substantially increase in connection with our ongoing activities, particularly as we advance development of our lead clinical product candidate, arhalofenate, for the prevention of gout flares and the treatment of hyperuricemia in patients with gout.

In the event we do not successfully raise sufficient funds in financing our product development activities, particularly related to the ongoing development of arhalofenate and planned development of MBX-8025, it will be necessary to curtail our product development activities commensurate with the magnitude of the shortfall or our product development activities may cease altogether. To the extent that the costs of the ongoing Phase 2b study of arhalofenate in patients with gout exceed our current estimates and we are unable to raise sufficient additional capital to cover such additional costs, we will need to reduce operating expenses, enter into a collaboration or other similar arrangement with respect to development and/or commercialization rights to arhalofenate, outlicense intellectual property rights to arhalofenate, sell assets or effect a combination of the above. No assurance can be given that we will be able to effect any of such transactions on acceptable terms, if at all. Failure to progress the development of arhalofenate and MBX-8025 will have a negative effect on our business, future prospects and ability to obtain further financing on acceptable terms (if at all).

Beyond the plan of operations outlined above, our future funding requirements and sources will depend on many factors, including but not limited to the following:

- the rate of progress and cost of our clinical studies, including in particular the Phase 3 studies of arhalofenate and planned proof-of-concept studies of MBX-8025;
- the need for additional or expanded clinical studies;
- the rate of progress and cost of our Chemistry, Manufacturing and Control registration and validation program;
- the timing, economic and other terms of any licensing, collaboration or other similar arrangement into which we may enter;
- the costs and timing of seeking and obtaining FDA and other regulatory approvals;
- the extent of our other development activities;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the effect of competing products and market developments.

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

We have incurred significant losses since our inception. We anticipate that we will continue to incur significant losses for the foreseeable future, and we may never achieve or maintain profitability.

We have incurred significant net losses in each year since our inception, including net losses of approximately $31.9 million and $10.1 million for the fiscal years ended 2014 and 2013, respectively. As of December 31, 2014, we had an accumulated deficit of $380.8 million.

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

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

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

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

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

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

Our ability to generate revenue and achieve profitability depends on our ability, alone or with collaborators, to successfully complete the development, obtain the necessary regulatory approvals and commercialize our

product candidates. We do not anticipate generating revenues from sales of our product candidates for the foreseeable future, if ever. Our ability to generate future revenues from product sales depends heavily on our success in:

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

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

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

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

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

In order to raise additional funds to support our operations, we may sell additional equity or debt securities, enter into collaborations, strategic alliances, or licensing arrangements or other marketing or distribution arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interests 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 will impose limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

If we raise additional funds through collaborations, strategic alliances, or licensing arrangements or other marketing or distribution arrangements with third parties, we may have to relinquish valuable rights to our

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

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

We are an emerging growth company. Under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We plan to avail ourselves of this exemption from new or revised accounting standards and, therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not "emerging growth companies."

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

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

Risks Related to Clinical Development and Regulatory Approval

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

We have not marketed, distributed or sold any products. The success of our business depends upon our ability to develop and commercialize our lead product candidate, arhalofenate, which has completed eight Phase 1 and nine Phase 2 clinical trials, including five Phase 2 studies in gout, and our second product candidate, MBX-8025, which has completed five Phase 1 and one Phase 2 clinical trials. We are currently planning to meet with the FDA at an end of phase 2 meeting prior to finalizing plans for and initiating a Phase 3 program for

arhalofenate in gout. There is no guarantee that our clinical trials will be completed or, if completed, will be successful. We also plan to initiate one or more proof-of-concept studies for MBX-8025 in the first half of 2015. The success of arhalofenate and MBX-8025 will depend on several factors, including the following:

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

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

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

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

We currently do not know when we might commence our Phase 3 study of arhalofenate or achieve FDA approval of arhalofenate. We currently do not have the capital necessary to conduct or complete Phase 3 studies of arhalofenate and we may not be able to raise sufficient funds necessary or secure a partnership to conduct this study.

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

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

Before obtaining regulatory approval for the sale of our product candidates, including arhalofenate and MBX-8025, we must conduct additional clinical trials to demonstrate the safety and efficacy of our product

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

We have completed five Phase 2 clinical studies of arhalofenate in gout. In addition, six clinical studies with MBX-8025 and five clinical studies with MBX-2982 have been completed. However, we have never conducted a Phase 3 clinical trial. The positive results we have seen to date in our Phase 2 clinical trials of arhalofenate for gout do not ensure that later clinical trials will demonstrate similar results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed satisfactorily through preclinical studies and initial clinical testing. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience, have suffered significant setbacks in Phase 3 clinical development, even after seeing promising results in earlier clinical trials.

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

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the clinical study protocol may require one or more amendments delaying study completion;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate or subjects may drop out of these clinical trials at a higher rate than we anticipate;
- clinical investigators or study subjects fail to comply with clinical study protocols;
- trial conduct and data analysis errors may occur, including, but not limited to, data entry and/or labeling errors;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our clinical trial materials or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators to suspend or terminate the trials.

We expect our research and development expenses to increase in connection with our ongoing activities, particularly if we commence a Phase 3 clinical trial with arhalofenate and undertake additional clinical trials of our other product candidates MBX-8025 and MBX-2982. Before we commence a Phase 3 clinical trial for

arhalofenate, we will need to raise substantial additional capital. We also will need to raise substantial additional capital in the future to complete the development and commercialization of MBX-8025 and MBX-2982, for which we currently have no planned clinical trials. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds required to complete research and development and commercialize our products under development.

Negative or inconclusive results of our future clinical trials of arhalofenate, or any other clinical trial we conduct, could cause the FDA to require that we repeat or conduct additional clinical studies. Despite the results reported in earlier clinical trials for arhalofenate, we do not know whether any clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates, including arhalofenate. If later stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for our product candidates, including arhalofenate, may be adversely impacted.

We have never conducted a clinical trial of MBX-8025 for the indications which we are considering for MBX-8025. If MBX-8025 does not demonstrate safety or efficacy in the treatment of any of these indications, or if the benefits of treatment with MBX-8025 do not outweigh the risks, our ability to successfully develop and commercialize MBX-8025 may be adversely affected.

We have not previously conducted a clinical trial of MBX-8025 for any of the indications for which we currently are considering. As a result, although we believe that MBX-8025 may be beneficial to address the diseases for which we are considering redirecting its development , there is no guarantee that MBX-8025 will prove to be safe or efficacious in the treatment of these diseases, or that we will be able to obtain FDA approval for these indications. The results of these clinical studies and other nonclinical studies may determine whether the benefits perceived from the use of MBX-8025 would outweigh the risks perceived from treatment with MBX-8025.

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

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

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

- inability to raise funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA on final trial design;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical trial sites;
- delays in obtaining required institutional review board (IRB) approval at each site;
- delays in recruiting suitable patients to participate in a trial;
- delays in having subjects complete participation in a trial or return for post-treatment follow-up;
- delays caused by subjects dropping out of a trial due to side effects or otherwise;
- delays caused by clinical sites dropping out of a trial;

- time required to add new clinical sites; and
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials.

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

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

Arhalofenate has been studied in a total of 17 clinical trials with over a thousand subjects. The emergence of adverse events (AEs) caused by arhalofenate in future studies could cause us, other reviewing entities, clinical study sites or regulatory authorities to interrupt, delay or halt clinical studies and could result in the denial of regulatory approval. There is also a risk that our other product candidates, including MBX-8025, may induce AEs, many of which may be unknown at this time. If an unacceptable frequency and/or severity of AEs are reported in our clinical trials for our product candidates, our ability to obtain regulatory approval for product candidates, including arhalofenate and MBX-8025, may be negatively impacted.

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

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution in a form of a modified risk evaluation and mitigation strategy;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications that could diminish the usage of the product or otherwise limit the commercial success of the affected product;
- we may be required to change the way the product is administered or to conduct additional clinical studies;
- we may choose to discontinue sale of the product;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

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

Regulatory authorities in some jurisdictions, including the United States and the European Union, or EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA or the European Medicines Agency, or EMA, from approving another marketing application for the same drug for that time period. The applicable period is seven years in the United States and ten years in

the European Union. The EU exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. In addition, the orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process. Also, regulatory approval for any product candidate may be withdrawn and other candidates may obtain approval before us. We have not obtained orphan designation for MBX-8025 for any indication, and may not be able to obtain designation or any of the potential benefits associated with it. Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the candidate from competition because different drugs can be approved for the same condition and the first entity with an orphan drug designation to receive regulatory approval for a particular indication will receive marketing exclusivity. Even after an orphan drug is approved, the FDA can subsequently approve another drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

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

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

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

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

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

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

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

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

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

- we may be unable to demonstrate to the satisfaction of regulatory authorities that a product candidate is safe and effective for any indication;
- regulatory authorities may not find the data from nonclinical studies and clinical studies sufficient or may differ in the interpretation of the data;
- regulatory authorities may require additional nonclinical or clinical studies;
- the FDA or foreign regulatory authority might not approve our third party manufacturers' processes or facilities for clinical or commercial product;
- the FDA or foreign regulatory authority may change its approval policies or adopt new regulations;
- the FDA or foreign regulatory authorities may disagree with the design or implementation of our clinical studies;
- the FDA or foreign regulatory authority may not accept clinical data from studies that are conducted in countries where the standard of care is potentially different from that in the U.S.;

- the results of clinical studies may not meet the level of statistical significance required by the FDA or foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks; and
- the data collection from clinical studies of our product candidates may not be sufficient to support the submission of a NDA or other submission or to obtain regulatory approval in the U.S. or elsewhere.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

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

Risks Related to Our Reliance on Third Parties

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

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

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

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

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

It is our expectation that only one supplier of drug substance and one supplier of drug product will be qualified by the FDA. If supply from an approved vendor is interrupted, there could be a significant disruption in commercial supply of arhalofenate. An alternative vendor would need to be qualified through an NDA supplement which would be expensive and could result in further delay. The FDA or other regulatory agencies outside of the U.S. may also require additional studies if a new drug substance or drug product supplier is relied

upon for commercial production. These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of arhalofenate, and cause us to incur additional costs. Furthermore, if our suppliers fail to deliver the required commercial quantities of active pharmaceutical ingredient on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our supply chain for arhalofenate may be delayed, which could inhibit our ability to generate revenues.

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

We are increasing the manufacturing batch size in preparation of Phase 3 and commercial supplies. As the process is scaled up it may reveal manufacturing challenges or previously unknown impurities which could require resolution in order to proceed with our planned clinical trials and obtain regulatory approval for the commercial marketing of arhalofenate. In the future, we may identify manufacturing issues or impurities which could result in delays in the clinical program and regulatory approval for arhalofenate, increases in our operating expenses, or failure to obtain or maintain approval for arhalofenate.

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

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

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

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

We rely on contract service providers (CSPs) including clinical research organizations, clinical trial sites, central laboratories and other service providers to ensure the proper and timely conduct of our clinical trials. While we have agreements governing their activities, we have limited influence over their actual performance.

We have relied and plan to continue to rely upon CSPs to monitor and manage data for our ongoing clinical programs for arhalofenate and our other product candidates, as well as the execution of nonclinical studies. We control only certain aspects of our CSPs' activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CSPs does not relieve us of our regulatory responsibilities.

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

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

Risks Related to Commercialization of Our Product Candidates

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

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

- demonstration of clinical safety and efficacy in our clinical trials;
- the risk/benefit profile of our products such as arhalofenate;
- the relative convenience, ease of administration and acceptance by physicians, patients and health care payors;
- the prevalence and severity of any side effects;

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

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

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

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

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

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

In addition, there are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not

occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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

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

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

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

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

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

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

- research and development resources, including personnel and technology;
- regulatory experience;

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

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

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

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

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

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

In addition, there may be significant delays in obtaining reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or health authorities in other countries. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be

made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government health care programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the U.S. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies.

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

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

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

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

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

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

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

We do carry product liability insurance for our clinical studies. Further, we intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for any of our product candidates. However, we may be unable to obtain this product liability insurance on commercially reasonable

terms and with insurance coverage that will be adequate to satisfy any liability that may arise. On occasion, large judgments have been awarded in class action or individual lawsuits relating to marketed pharmaceuticals. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

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

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

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

We are planning to study the combination of arhalofenate plus febuxostat in our planned Phase 3 program and if the results of these studies are positive, we will only be able to commercialize this combination if we are able to obtain febuxostat from an FDA qualified supplier, which we may not be able to do.

In order to commercialize a fixed dose combination product containing arhalofenate and febuxostat we would need to obtain febuxostat drug substance from a supplier that has been qualified by the FDA. If we are not able to identify a supplier, or if the supplier is not able to receive approval, we will not be able to receive approval for our fixed-dose combination product. In addition, we may need a license if the supplier's manufacturing process or final product infringes another party's valid patent. If we are not successful at obtaining a required license our ability to commercialize arhalofenate may be significantly diminished.

Risks Related to Our Intellectual Property

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

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

development or regulatory approvals, the period of time during which we could market arhalofenate under patent protection could be reduced. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file any patent application related to arhalofenate or our other product candidates. Furthermore, if third parties have filed such patent applications, an interference proceeding in the U.S. can be provoked by a third party or instituted by us to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license it from the prevailing party, which may not be available on commercially reasonable terms or at all.

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

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

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

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

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of arhalofenate and/or our other product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any

such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

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

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

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

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

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

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

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

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

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

Risks Related to Our Business Operations and Industry

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

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

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

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

As of March 1, 2015, we had 18 full-time employees. As our company matures, we expect to expand our employee base to increase our managerial, clinical, scientific and engineering, operational, sales, and marketing teams. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize arhalofenate and our other product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Our internal computer systems, or those used by our contract research organizations or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our contract research organizations and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product candidate development programs. For example, the loss of clinical study data from completed or ongoing clinical studies for a product candidate could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of any product candidates could be delayed.

Risks Relating to Owning Our Common Stock

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

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

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

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

- adverse results or delays in preclinical testing or clinical trials;
- inability to obtain additional funding;

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

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

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

As of March 1, 2015, our executive officers, directors and stockholders who own more than 5% of our outstanding common stock, together beneficially own a significant number of shares of our common stock. Therefore, these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments to our organizational documents, or approval of any merger, sale of assets, or other major corporate action. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

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

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

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

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. For example, on July 28, 2014, we consummated a public offering of our common stock on a registration statement on Form S-1pursuant to which we sold 4,600,000 shares of our common stock, including shares sold in connection with the exercise by the underwriters in the offering of an over-allotment of 600,000 shares, at a price of $5.50 per share, for aggregate net proceeds of $23.0 million. On November 7, 2014, we filed a $100 million registration statement on Form S-3 with the SEC and also entered into an ATM to sell up to $25 million of common stock under the registration statement under which we have sold additional shares of our common stock for net proceeds to us of $4.3 million during the period January 1, 2015 through March 1, 2015. If in the future, we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our equity incentive plans, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares available for future grant under our equity incentive plans as of March 1, 2015 was 330,192 shares.

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

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

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

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

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

Provisions in our amended and restated certificate of incorporation and our bylaws may delay or prevent an acquisition of us. In addition, these provisions may frustrate or prevent any attempts by our stockholders to

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

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

Maintaining effective internal controls over financial reporting is necessary for us to produce accurate financial statements on a timely basis. In connection with the preparation of our financial statements for the three and six months ended June 30, 2014, we identified material weaknesses in our internal control over financial reporting. In the second half of 2014, we remediated these material weaknesses by, among other things, designing and implementing new procedures and controls. We expect to continue to incur costs associated with implementing appropriate processes and internal controls, which could include new employee compensation costs and fees for additional audit and consulting services, which could negatively affect our financial condition and operating results.

However, effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud. Our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act until the later of the year following our first annual report required to be filed with the SEC or the date we are no longer an “emerging growth company” as defined in the JOBS Act, because we are taking advantage of the exemptions contained in the JOBS Act. To build the infrastructure to allow us to assess the effectiveness of our internal control over financial reporting, we hired our Controller in the first quarter of 2014 to assist us in improving our accounting systems, disclosure policies, procedures and controls. This effort is on-going and will be costly and time consuming. If we are unsuccessful in building an appropriate accounting infrastructure, we may not be able to prepare and disclose, in a timely manner, our financial statements and other required disclosures, or comply with existing or new reporting requirements. We cannot assure you that there will not be material weaknesses in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to achieve effective internal control over financial reporting, or if our independent registered public accounting firm determines we continue to have a material weakness in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by The NASDAQ Stock Market, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our corporate office is located in Newark, California. We entered into a lease for our corporate office in November 2013 which commenced on January 16, 2014, and continues for a period of sixty (60) months with an option to extend the lease for an additional three years. Our previous corporate office was located at a facility in Hayward, California and was subject to a lease which expired in April 2014. We believe that our existing facility arrangements are adequate to meet our current requirements.

Item 3. Legal Proceedings

We are not a party to any legal proceedings.

Item 4. Mine Safety Disclosures

Not Applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market for Common Equity

Our common stock is listed on the NASDAQ Capital Market under the symbol "CBAY" and was previously traded over-the-counter from January 24, 2014, until June 17, 2014. Prior to such time, there was no public market for our common stock. On March 20, 2015, the last reported sale price of our common stock on the NASDAQ Capital Market was $8.96 per share. As of March 1, 2015, there were approximately 890 holders of record of our common stock.

The following table sets forth the high and low sales prices per share of our common stock as reported on the over-the-counter and NASDAQ Capital Market for the periods indicated. Such quotations represent inter-dealer prices without retail markup, markdown or commission and may not necessarily represent actual transactions.

Year Ended December 31, 2014	High	Low
First Quarter (beginning January 24, 2014)	$12.00	$5.00
Second Quarter*	$ 8.00	$5.05
Third Quarter	$13.78	$4.47
Fourth Quarter	$ 9.99	$6.59

* Our common stock traded on the over-the-counter market until June 18, 2014

Dividend Policy

We have never declared or paid any cash dividends to our stockholders. Our board of directors will make any future decisions regarding dividends. We currently intend to retain and use any future earnings, if any, for the development and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Our board of directors has complete discretion on whether to pay dividends. Even if our board of directors decides to pay dividends, the form, frequency and amount will depend upon our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that the board of directors may deem relevant. Further, we may not pay dividends or redeem shares of our capital stock without the prior consent of the lenders pursuant to the terms of our current loan and security agreement with Silicon Valley Bank.

Recent Sales of Unregistered Securities

We completed sales of the following unregistered securities during the quarter ended December 31, 2014:

1) From October 1, 2014, to December 31, 2014, we issued an aggregate of 11,220 shares of common stock to 7 of our stockholders upon the exercise of warrants exercisable for shares of our common stock. The 11,220 shares of common stock were issued pursuant to cash-based and cashless exercise provisions as provided in the warrants in exchange for an aggregate of $46,000 and 3,220 shares of our common stock. The issuances were in reliance on Rule 506 and Regulation D under the Securities Act.

Use of Proceeds

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

As of December 31, 2014, we estimate that we had used approximately $8.5 million of the proceeds on the development of MBX-8025 and ongoing development of arhalofenate and approximately $1.5 million for working capital, capital expenditures and other general corporate purposes. The remaining $13.0 million is held in cash, cash equivalents and short term investments. There has been no material change in the expected use of the net proceeds from our public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) on July 22, 2014 (File No. 333-195127).

Issuer Purchases of Equity Securities

During the quarter ended December 31, 2014, we did not repurchase any equity securities.

Item 6. Selected Financial Data

Not applicable

Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations*

Forward-Looking Statements

Some of the statements under in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" are forward-looking statements. These forward-looking statements are based on management's beliefs and assumptions and on information currently available to our management and involve significant elements of subjective judgment and analysis. Words such as "may," "will," "should," "could," "would," "expect," "plan," "anticipate," "believe," "estimate," "project," "predict," "potential," "seek" "target," "goals," "intend," variations of such words, and similar expressions are intended to identify forward-looking statements. Our actual results and the timing of events may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such a difference include those discussed under the caption "Special Note Regarding Forward Looking Statements" and in "Risk Factors" and elsewhere in this Annual Report on Form 10-K. 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 Annual Report.

Overview

CymaBay Therapeutics, Inc. is focused on developing therapies to treat metabolic diseases with high unmet medical need, including serious rare and orphan disorders. Arhalofenate, our lead product candidate, is being developed for the treatment of gout. Arhalofenate has successfully completed five Phase 2 clinical trials in patients with gout and consistently demonstrated the ability to reduce gout flares and reduce serum uric acid (sUA). Gout flares are recurring and painful episodes of joint inflammation that are triggered by the presence of monosodium urate crystals that form as a result of elevated sUA levels. We believe the potential for arhalofenate to prevent or reduce flares while also lowering sUA could differentiate it from currently available treatments for gout and classify it as the first potential drug in what we believe could be a new class of gout therapy referred to as Urate Lowering Anti-Flare Therapy (ULAFT). Arhalofenate has established a favorable safety profile in

clinical trials involving over 1,000 patients exposed to date. We are currently planning to hold an end of phase 2 meeting with the FDA in the second half of 2015 to review the results of our completed studies and to discuss the design of a phase 3 program for arhalofenate. Our second product candidate, MBX-8025, demonstrated favorable effects on cholesterol, triglycerides and markers of liver health in a Phase 2 clinical trial in patients with mixed dyslipidemia. We are planning to pursue development of MBX-8025 in a number of orphan diseases in which these attributes could be beneficial, such as homozygous familial hypercholestorolemia (HoFH), primary biliary cirrhosis (PBC) and severe hypertriglyceridemia (SHTG). We also believe that MBX-8025 could have utility in the treatment of the more prevalent, but high unmet need, indication of nonalcoholic steatohepatitis (NASH). We plan to initiate one or more pilot or proof-of-concept studies for MBX-8025, beginning with HoFH, in the first half of 2015.

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

Preferred Stock Conversion and Recent Financings

On September 30, 2013, all of the shares of our outstanding preferred stock converted to common stock, we sold shares of our common stock and warrants to purchase shares of our common stock in a private placement for aggregate gross proceeds of $26.8 million, and raised an additional $5.0 million in venture debt financing pursuant to a $10.0 million loan agreement which we entered into simultaneously with the private placement, resulting in aggregate net proceeds to us of $28.8 million after deducting placement agent fees and estimated offering expenses. At the same time we issued shares of our common stock in cancellation of approximately $16.9 million of debt owed to the holder of that debt. On October 31, 2013, we sold additional shares of our common stock and warrants to purchase shares of our common stock, which sales are also part of the private placement, for net proceeds to us of $2.2 million after deducting placement agent fees and estimated offering expenses. Further, on November 22, 2013, we entered into an agreement with investors to purchase shares of our common stock and warrants to purchase shares of our common stock as part of the private placement for net proceeds of $2.7 million, which sales occurred shortly after the listing of our common stock on the over-the-counter market on January 24, 2014. We refer to the private placement, the venture debt financing and the issuance of our common stock in cancellation of the $16.9 million of debt as our 2013 financing

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

On November 7, 2014, we filed a $100 million registration statement on Form S-3 with the SEC and also entered into an at-the-market facility (ATM) to sell up to $25 million of common stock under the registration statement, under which, as of March 1, 2015, we have sold shares of common stock with aggregate net proceeds to us of $4.3 million.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. We base our estimates on historical experience and on various other factors that we believe to be materially reasonable under the circumstances, 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.

While our significant accounting policies are described in more detail in Note 2 of our financial statements included in this Annual Report, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation and understanding of our financial statements.

Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing contracts, reviewing the terms of our license agreements, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees to:

- contract research organizations and other service providers in connection with clinical studies;
- contract manufacturers in connection with the production of clinical trial materials; and
- vendors in connection with preclinical development activities.

We base our expenses related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows and expense recognition. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed 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 our estimate, we adjust the accrual accordingly. Our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in our reporting changes in estimates in any particular period. Adjustments to prior period estimates have not been material for the years ended December 31, 2014, and 2013.

Stock-Based Compensation

Employee and director stock-based compensation is measured at the grant date, based on the fair-value based measurements of the stock awards, and the portion that is ultimately expected to vest is recognized as an expense over the related vesting periods, net of estimated forfeitures. We calculate the fair-value based measurements of options using the Black-Scholes valuation model and recognize expense using the straight-line attribution method.

The Black-Scholes option pricing model requires the input of highly subjective assumptions. These variables include, but are not limited to, our stock price volatility over the term of the awards, and actual and projected employee stock option exercise behaviors. Because our employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect fair value estimates, in management's opinion, the existing models may not provide a reliable single measure of the fair value of our employee stock. In addition, management continually assesses the assumptions and methodologies used to calculate the estimated fair value of stock-based compensation. Circumstances may change and additional data may become available over time, which could result in changes to the assumptions and methodologies, and which could materially impact our fair value determination, as well as our stock-based compensation expense.

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

Common Stock Valuations

Prior to the listing of our common stock on a public exchange on January 24, 2014, the fair value of the common stock underlying our stock options and restricted stock at the date of grant was determined by our board of directors, which intended all options granted to be exercisable at a price per share not less than the per share fair value of our common stock underlying those options on the date of grant. All stock awards previously granted or to be granted in the future were or are expected to be granted at the grant date fair value of the award. The valuations of our common stock while we were privately held were determined in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Valuation analysis of our common stock was performed on our behalf by third party valuation specialists. The methodology used by the third party valuation specialists to determine the fair value of our common stock included estimating the fair value of the enterprise, subtracting the fair value of debt from this enterprise value, and then allocating this value using the Option Pricing Method to all of the equity interests. The assumptions used in the valuation model to determine the fair value of our common stock as of the date of each option and restricted stock award, are based on numerous objective and subjective factors combined with management judgment including the following:

- progress of research and development activities;
- our operating and financial performance;
- market conditions;
- developmental milestones achieved;
- sales of our convertible preferred stock in arms-length transactions;
- business risks; and
- management and board of director experience.

During the period from January 1, 2013, through January 24, 2014, the time frame during the reporting period where we were still a privately held company, we granted stock options as summarized below:

Date of Issuance	Number of Shares Subject to Options Granted	Exercise Price per Share	Fair Value Estimate per Common Share	Estimated Total Fair Value-Based Measurement of Options Granted (In thousands)
October 31, 2013	321,574	$ 5.00	$ 3.75	$ 1,207
December 23, 2013	166,123	$ 5.00	$ 3.77	$ 600
January 6, 2014	320,991	$ 5.00	$ 3.75	$ 1,203
January 22, 2014	19,459	$ 5.00	$ 3.77	$ 73

While we were privately held, management and our board of directors performed valuation analyses with the assistance of independent valuation specialists to determine the then current fair value of our common stock. To facilitate these valuation analyses, we developed projections of our future revenues and operating expenses. Key assumptions reflected in the income approach calculations included the anticipated timing of a potential liquidity event, the estimated volatility of our common stock, and the discount for lack of marketability of our common stock. These income approach assumptions are set forth below for the valuation performed as of December 31, 2013:

Common Stock Value per Share	$5.00
Time to Liquidity (in years)	0.25
Volatility	64.6%
Risk-Free Interest Rate	0.02%
Marketability Discount Rate	12.8%

For grants of stock awards made on dates for which there was no valuation performed by an independent valuation specialist, our board of directors determined the fair value of our common stock on the date of grant based upon the immediately preceding valuation and other pertinent information available to it at the time of grant.

Warrant Liabilities

We have issued freestanding warrants to purchase shares of our common stock in connection with financing activities. Our outstanding common stock warrants issued in connection with our 2013 financing are classified as liabilities in the balance sheet as they contain terms for redemption of the underlying security that are outside our control We use a binomial lattice option pricing model to value warrants, which requires management to estimate inputs including expected volatility and expected term, and is most significantly impacted by our common stock price. These inputs are inherently subjective and require significant analysis and judgment to develop. The fair value of all warrants is re-measured at each financial reporting date with any changes in fair value being recognized in change in fair value of warrant liabilities, a component of other income (expense), in the statements of operations and comprehensive income (loss). We will continue to re-measure the fair value of the warrant liabilities until exercise or expiration of the related warrant.

Results of Operations

General

To date, we have not generated any net income from operations. As of December 31, 2014, we have an accumulated deficit of $380.8 million, primarily as a result of expenditures for research and development and general and administrative expenses. While we may in the future generate revenue from a variety of sources, including license fees and milestone payments in connection with strategic partnerships, our product candidates are at a mid-level stage of development and may never be successfully developed or commercialized. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future and there can be no assurance that we will ever generate sufficient revenue to achieve and sustain profitability.

Research & Development Expenses

Conducting research and development is central to our business model. For the years ended December 31, 2014 and 2013, research and development expenses were $15.8 million and $4.5 million, respectively. Research and development expenses are detailed in the table below:

	Year Ended December 31,	
($ in thousands)	**2014**	**2013**
Arhalofenate – Phase 2b Randomized Study	$ 7,630	$ 461
Arhalofenate – Febuxostat Combo Study	978	—
Arhalofenate Gout – Drug manufacturing	1,279	—
Arhalofenate Gout – Three Phase 2 Randomized Studies	(90)	640
MBX-8025	1,766	—
Other Projects	61	68
Total Project Costs	11,624	1,169
Internal Research and Development Costs	4,199	3,356
Total Research and Development	$15,823	$4,525

Our external research and development costs consist primarily of:

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

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

We expect to continue to incur substantial expenses related to our development activities for the foreseeable future as we continue product development and initiate additional clinical studies for arhalofenate and MBX-8025. Since product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later stage clinical trials, we expect that our research and development expenses will increase in the future.

General and Administrative Expenses

General and administrative expenses consist principally of personnel-related costs, professional fees for legal, consulting, audit services, rent and other general operating expenses not otherwise included in research and development. For the years ended December 31, 2014 and 2013, general and administrative expenses were $8.2 million and $4.9 million, respectively. We anticipate that in future periods, general and administrative expenses will remain consistent with current expenditure levels, reflecting the fact that we have sufficiently expanded our infrastructure and retained professional and other outside services necessary to support our operations as an emerging growth company under the JOBS Act.

Comparison of Years Ended December 31, 2014 and 2013

	Year Ended December 31,		
	2014	2013	Variance
($ in thousands)			
Operating expenses:			
Research and development	$ 15,823	$ 4,525	$ 11,298
General and administrative	8,185	4,871	3,314
Loss from operations	(24,008)	(9,396)	(14,612)
Interest expense, net	(681)	(812)	131
Other income (expense), net	(7,228)	135	(7,363)
Net loss	$(31,917)	$(10,073)	$(21,844)

Research and development expenses increased $11.3 million, from $4.5 million to $15.8 million for the years ended December 31, 2013 and 2014, respectively. Total project costs increased by $10.5 million for the year ended December 31, 2014, as compared to December 31, 2013, primarily due to ongoing Phase 2b clinical trial activities for arhalofenate. Specifically, substantial costs were incurred for clinical research services performed by our CRO partner to coordinate patient dosing visits at investigator sites, patient sample testing, data collection and analysis, and other clinical trial activities. In addition, toxicology studies and other preclinical activities were initiated in 2014 to support the development of MBX-8025. Internal research and development cost increased by $0.8 million for year ended December 31, 2014, as compared to December 31, 2013, due to increased employee compensation, recruiting and consulting costs incurred to support our expanded research and development activities.

General and administrative expenses consist principally of personnel-related costs, professional fees for legal, consulting, audit services, rent and other general operating expenses not otherwise included in research and development. General and administrative expenses increased by $3.3 million, from $4.9 million to $8.2 million, for the years ended December 31, 2013 and 2014, respectively, primarily due to higher employee compensation of $1.6 million, professional and consulting fees of $1.4 million, and insurance and other administrative costs of $0.3 million, primarily as a result of becoming a publicly traded company.

Other income (expense), net reflected a loss of $7.2 million for the year ended December 31, 2014, as compared to a gain of $0.1 million for the year ended December 31, 2013, due primarily to the re-measurement of our warrant liabilities at fair value as of December 31, 2014, as compared to the fair value re-measurement of our warrants at December 31, 2013. At each reporting date, we use a binomial lattice option pricing model to value warrants we issued in connection with our 2013 financing. The warrant valuation in 2014 changed primarily due to an increase in the price of our common stock which is one of several inputs to our valuation model. Specifically, the $7.2 million warrant revaluation loss recognized during the year ended December 31, 2014 was due primarily to an increase in the value of our common stock from $5.00 at December 31, 2013, to $9.83 at December 31, 2014. During the year ended December 31, 2013, a warrant revaluation loss of $0.5 million was recorded. The 2013 revaluation loss was not as significant since the warrants were issued on September 30, 2013, and were only outstanding for the three months ended December 31, 2013. During this shortened period binomial model inputs did not change significantly.

Income Taxes

As of December 31, 2014, we had federal net operating loss carryforwards of $181.0 million and state net operating loss carryforwards of $164.6 million to offset future taxable income, if any. In addition, we had federal research and development tax credit carry forwards of $6.7 million and state research and development tax credit carryforwards of $3.2 million. If not utilized, the federal net operating loss and tax credit carryforwards will

expire beginning in 2024 through 2034 and the state net operating loss carryforwards will expire beginning in 2015 through 2034 (specifically, $17.3 million of state net operating losses will expire in 2015). The state tax credit will carry forward indefinitely. Current federal and state tax laws include substantial restrictions on the utilization of net operating losses and tax credits in the event of an ownership change. Even if the carryforwards are available, they may be subject to annual limitations, lack of future taxable income, or future ownership changes that could result in the expiration of the carryforwards before they are utilized. At December 31, 2014, we recorded a 100% valuation allowance against our deferred assets of approximately $102.0 million as our management believes it is more likely than not that they will not be fully realized. If we determine in the future that we will be able to realize all or a portion of our net operating loss carryforwards, an adjustment to our net operating loss carryforwards would increase net income in the period in which we make such a determination.

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 December 31, 2014, we had cash, cash equivalents and marketable securities of $34.8 million, primarily as a result of the aggregate proceeds received in our 2013 financing and 2014 public offering.

Specifically, on September 30, 2013, we issued common stock and warrants to purchase our common stock and we secured a term loan facility which together enabled us to raise aggregate net proceeds of $28.8 million. On September 30, 2013, all of the shares of our outstanding redeemable convertible preferred stock converted to common stock, and we sold shares of our common stock and warrants to purchase shares of our common stock in a private placement for aggregate gross proceeds of $26.8 million, and raised an additional $5.0 million in venture debt financing pursuant to a $10.0 million loan agreement which we entered into simultaneously with the private placement, resulting in aggregate net proceeds to us of $28.8 million after deducting placement agent fees and offering expenses. At the same time we issued shares of our common stock in cancellation of approximately $16.9 million of debt owed to the holder of that debt and on October 31, 2013, we issued common stock and warrants to purchase our common stock to raise additional net proceeds of $2.2 million. Furthermore, on November 22, 2013, we entered into an agreement with investors to purchase shares of our common stock and warrants to purchase our common stock as part of the private placement for net proceeds of $2.7 million, which sales occurred shortly after our listing of our common stock on the over-the-counter market on January 24, 2014.

On July 28, 2014, we completed a public offering of 4.6 million shares of our common stock at $5.50 per share. Net proceeds to us in connection with the 2014 public offering were approximately $23.0 million after deducting underwriting discounts, commissions and offering expenses

Term Loan Facility

The venture debt financing referenced in the 2013 financing was provided to us pursuant to a term loan facility with Silicon Valley Bank and Oxford Finance LLC, collectively referred to as the lenders, for an aggregate amount of $10 million, of which $5 million was made available to us as of September 30, 2013, and the remaining $5 million, referred to as the second tranche, which became available to us on February 24, 2015, when we announced the achievement of positive data and successful completion of all primary endpoints for either the 600 mg or 800 mg dose of arhalofenate in our planned Phase 2b study (the “second draw milestone”). The second tranche shall be available to us until the earlier of June 30, 2015, or the occurrence and continuation of an event of default (as described in the term loan facility). Each tranche matures 48 months following the funding date of such tranche. The proceeds of the term loan facility may be used for general corporate purposes.

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

We are permitted to make voluntary prepayments of the term loans with a prepayment fee equal to 3% of the term loans prepaid. On each tranche, we are required to make 12 monthly interest only payments after the funding date followed by a repayment schedule equal to 36 equal monthly payments of the outstanding principal of the outstanding term loans of each tranche. After the 36-month amortization period of each tranche, the remaining balance of such tranche and a final payment equal to 6.50% of the original principal amount of the applicable tranche are payable on the maturity date of such tranche. We are required to make mandatory prepayments of the outstanding term loans upon the acceleration by the lenders of such loans following the occurrence of an event of default, along with a payment of the final payment, the prepayment fee and any other obligations (each as defined or described under the term loan facility) that are due and payable at the time of the prepayment.

Our obligations under the term loan facility are secured, subject to customary permitted liens and other agreed upon exceptions, (1) by a first priority pledge of all of the equity interests of each of our direct and indirect subsidiaries, and (2) a perfected first priority interest in all of our tangible and intangible assets, including all of our intellectual property.

The term loan facility contains customary representations and warranties and customary affirmative and negative covenants applicable to us and our subsidiaries, including, among other things, restrictions on dispositions, changes in business, management, ownership or business locations, mergers or acquisitions, indebtedness, encumbrances, distributions, investments, transactions with affiliates and subordinated debt. Until the occurrence of the second draw milestone, the term loan facility contains financial covenants that require us to maintain a certain cash liquidity. The term loan facility also contains performance covenants that require that by no later than April 30, 2015, the lenders must have received evidence of the occurrence of the second draw milestone; provided that our failure to comply with the performance covenant shall not be an event of default under the term loan facility so long as we deposit an amount equal to 100% of the aggregate outstanding term loans in a segregated, blocked deposit account at Silicon Valley Bank.

The term loan facility also includes customary events of default, including but not limited to the nonpayment of principal or interest, violations of covenants, material adverse change, attachment, levy, restraint on business, cross-defaults on our or any our subsidiary's material indebtedness, bankruptcy, material judgments and misrepresentations. Upon an event of default, the lenders may, among other things, accelerate the loans and foreclose on the collateral. As of December 31, 2014, we were in compliance with the terms of the term loan covenants and there were no identified events of default.

Shelf Registration and At-the-Market Facility

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

Cash Flows

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

	Year Ended December 31,	
	2014	2013
Net cash used in operating activities	$ (21,114)	$ (8,458)
Net cash used in investing activities	(16,938)	(6,231)
Net cash provided by financing activities	25,237	31,364
Net (decrease) increase in cash and cash equivalents	$ (12,815)	$ 16,675

Operating Activities: Cash used in operating activities for the years ended December 31, 2014, and December 31, 2013, was $21.1 million and $8.5 million, respectively. The increase of $12.6 million in cash used in operating activities is due primarily to our incurrence of research and development expenses as a result of our expanded clinical trial and drug development activities, and increased general and administrative expenses as a result of becoming a publicly traded company.

Investing Activities: Net cash used in investing activities was $16.9 million for the year ended December 31, 2014 and $6.2 million for the year ended December 31, 2013, and was primarily due to the purchase of marketable securities as we sought to invest funds raised in our equity and debt financings.

Financing Activities: Net cash provided by financing activities was $25.2 million in the year ended December 31, 2014, primarily due to $25.4 million of proceeds received from the sale of equity securities, offset by $0.2 million in principal repayments on our venture debt facility. Net cash provided by financing activities was $31.4 million in the year ended December 31, 2013, primarily due to $26.5 million of proceeds received from the sale of equity securities, and $4.9 million from the receipt of funds under our venture debt facility.

Capital Requirements

We have incurred operating losses since inception and had an accumulated deficit of $380.8 million at December 31, 2014. Management expects operating losses and negative cash flows to continue for the foreseeable future. As of December 31, 2014, we had $34.8 million in cash and cash equivalents and marketable securities, which is available to fund future operations. Taking into account the repayment of our outstanding debt classified within current liabilities on our balance sheet as of December 31, 2014, we anticipate that we will be required to seek additional equity or debt financing and/or non-dilutive funding from potential licensing deals to fund our operations through December 31, 2015. If we are unable to obtain additional funding during 2015, we will delay one or more of our planned development programs commencing early in the second half of 2015. Consistent with the actions we have taken in the past, we will prioritize necessary and appropriate steps to enable the continued operations of the business and preservation of the value of our assets beyond the next twelve months, including but not limited to actions such as reduced personnel-related costs, additional curtailment of our development activities and other discretionary expenditures that are within our control. These reductions in expenditures, if required, may have an adverse impact on our ability to achieve certain planned objectives during 2015. In addition to seeking equity or debt financing, we may seek to access additional capital to support future operations through licensing, partnering or other strategic collaborative arrangements. It is unclear if or when any such transactions will occur, on satisfactory terms or at all.

Off Balance Sheet Arrangements

As of December 31, 2014, we had no off-balance sheet arrangements (as defined in Item 303(a)(4)(ii) of Regulation S-K under the Exchange Act) that create potential material risks for us and that are not recognized on our balance sheets.

Contractual Obligations

The following table summarizes our long-term contractual obligations as of December 31, 2014:

	Payments Due by Period			
(In thousands)	Total	Less than 1 Year	1-3 Years	3-5 Years
Contractual Obligations				
Operating lease obligations	875	209	666	—
Facility term loan, including interest	5,711	1,901	3,810	—
Contractual Commitments	$6,586	$ 2,110	$4,476	$ —

This compares to $7.6 million in long-term contractual obligations as of December 31, 2013.

In addition, we rely on contract research organizations and other research support providers to perform clinical and preclinical studies for us and we contract with firms to supply our drug compounds for use in our development activities. As of December 31, 2014, under the terms of our agreements with these organizations, we are obligated to make future payments as services are provided of approximately $6.0 million through 2016. These agreements are terminable by us upon written notice. Generally, we are only liable for actual effort expended or cost incurred by the organizations at any point in time during the contract period through the notice period.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 8. Financial Statements and Supplementary Data

The disclosure required in this Item 8 is included in Item 15, which information is incorporated by reference here.

Item 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure*

None.

Item 9A. *Controls and Procedures*

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

Management's Annual Report on Internal Control Over Financial Reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer 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 and includes those policies and procedures that (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on criteria established in "Internal Control—Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Our management concluded that our internal control over financial reporting was effective as of December 31, 2014.

Limitations on the Effectiveness of Controls. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the controls are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system

are met and, as set forth above, our chief executive officer and chief financial officer have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were not effective at the reasonable assurance level because of a material weakness in our internal control over financial reporting, as described below.

Changes in Internal Controls. There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2014, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, except as described below.

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

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

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

In the second half of 2014, we developed and implemented a remediation plan for this material weakness which includes, among other things, a secondary independent review of the warrant input values in the valuation report, a secondary independent review of our warrant liability reconciliation, and an enhanced warrant variance analysis to complement our review of our financial statements in an effort to detect and address timely warrant valuation related variance anomalies.

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

Item 9B. ***Other Information***

None.

PART III

Item 10. ***Directors, Executive Officers and Corporate Governance***

Identification of Executive Officers and Directors

Reference is made to the information regarding executive officers appearing under the heading "Business — Executive Officers of Registrant" in Part I Item 1 of this Annual Report on Form 10-K, which information is hereby incorporated by reference. Reference is made to the information regarding our directors and nominees for director appearing under the heading "Proposal 1 — Election of Directors" to be included in our proxy statement for our 2015 annual meeting of stockholders, or 2015 Proxy Statement, which information is hereby incorporated by reference.

Identification of Audit Committee and Audit Committee Financial Expert

Reference is made to the information regarding directors to be included under the headings "Information Regarding the Board of Directors and Corporate Governance — Information Regarding Committees of the Board of Directors— Audit Committee" in our 2015 Proxy Statement, which information is hereby incorporated by reference.

Material Changes to Procedures for Recommending Directors

Reference is made to the information regarding directors to be included under the heading "Information Regarding the Board of Directors and Corporate Governance" in our 2015 Proxy Statement, which information is hereby incorporated by reference.

Compliance with Section 16(a) of the Exchange Act

Reference is made to the information to be included under the heading "Section 16(a) Beneficial Ownership Reporting Compliance" in our 2015 Proxy Statement, which information is hereby incorporated by reference.

Code of Conduct

Reference is made to the information to be included under the heading "Information Regarding the Board of Directors and Corporate Governance — Code of Business Conduct and Ethics" in our 2015 Proxy Statement, which information is hereby incorporated by reference. A copy of our code of business conduct and ethics can be found on our website, http://ir.cymabay.com/governance-docs . The contents of our website are not a part of this Annual Report on Form 10-K.

Item 11. ***Executive Compensation***

Reference is made to the information to be included under the heading "Executive Compensation" in our 2015 Proxy Statement, which information is hereby incorporated by reference.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

Security Ownership

The information required by this item will be set forth in our 2015 Proxy Statement under the caption "Security Ownership of Certain Beneficial Owners and Management" and is incorporated herein by reference.

Equity Compensation Plan Information

Information concerning our equity compensation plans will be set forth in our 2015 Proxy Statement under the caption "Securities Authorized for Issuance under Equity Compensation Plans — Equity Compensation Plan Information" and is incorporated herein by reference.

Item 13. ***Certain Relationships and Related Transactions, and Director Independence***

The information required by this item will be set forth in our 2015 Proxy Statement under the captions "Transactions with Related Persons" and "Information Regarding the Board of Directors and Corporate Governance — Independence of the Board of Directors" and is incorporated herein by reference.

Item 14. ***Principal Accountant Fees and Services***

The information required by this item will be set forth in our 2015 Proxy Statement under the caption "Principal Accountant Fees and Services" and is incorporated herein by reference.

PART IV

Item 15. ***Exhibits, Financial Statement Schedules***

(a) Documents filed as part of this report

1. Financial Statements

2. Financial Statement Schedules

Financial statement schedules have been omitted in this report because they are not applicable, not required under the instructions, or the information requested is set forth in the financial statements or related notes thereto.

(b). List of Exhibits

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

CymaBay Therapeutics, Inc.
Index to Financial Statements

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of CymaBay Therapeutics Inc.

We have audited the accompanying balance sheets of CymaBay Therapeutics Inc. as of December 31, 2014 and 2013, and the related statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of CymaBay Therapeutics Inc. at December 31, 2014 and 2013, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Redwood City, California
March 23, 2015

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

	December 31, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 11,586	$ 24,401
Marketable securities	23,209	6,843
Contract receivables	211	110
Accrued interest receivable	136	68
Prepaid expenses	1,991	364
Other current assets	96	453
Total current assets	37,229	32,239
Property and equipment, net	86	3
Other assets	159	258
Total assets	$ 37,474	$ 32,500
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,085	$ 697
Accrued liabilities	3,388	2,251
Warrant liability	13,596	6,466
Facility loan	1,355	38
Accrued interest payable	35	36
Total current liabilities	20,459	9,488
Facility loan, less current portion	3,152	4,407
Other liabilites	13	9
Total liabilities	23,624	13,904
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value: 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.0001 par value: 100,000,000 shares authorized;14,696,108 and 9,455,064 shares issued and outstanding as of December 31, 2014 and December 31, 2013, respectively	1	1
Additional paid-in capital	394,622	367,435
Accumulated other comprehensive (loss) income	(14)	2
Accumulated deficit	(380,759)	(348,842)
Total stockholders' equity	13,850	18,596
Total liabilities and stockholders' equity	$ 37,474	$ 32,500

See accompanying notes.

CymaBay Therapeutics, Inc.
Statements of Operations and Comprehensive Loss
(In Thousands, except share and per share information)

	Year Ended December 31,	
	2014	2013
Operating expenses:		
Research and development	$ 15,823	$ 4,525
General and administrative	8,185	4,871
Total operating expenses	24,008	9,396
Loss from operations	(24,008)	(9,396)
Other income (expense):		
Interest income	74	10
Interest expense	(755)	(822)
Other income (expense), net	(7,228)	135
Net loss	$ (31,917)	$ (10,073)
Net (loss) income attributable to common stockholders	$ (31,917)	$ 243,994
Net loss	(31,917)	(10,073)
Other comprehensive loss:		
Unrealized (loss) gain on marketable securities	(16)	2
Other comprehensive loss	(16)	2
Comprehensive loss	$ (31,933)	$ (10,071)
Basic net (loss) income per common share	$ (2.65)	$ 103.52
Diluted net loss per common share	$ (2.65)	$ (3.54)
Weighted average common shares outstanding used to calculate basic net loss per common share	12,048,985	2,357,036
Weighted average common shares outstanding used to calculate diluted net loss per common share	12,048,985	2,845,609

See accompanying notes.

CymaBay Therapeutics, Inc.
Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In Thousands, except share and per share information)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balances as of December 31, 2012	661,059	$ 318,697	5,792	$ —	$ 913	$ —	$ (329,480)	$ (328,567)
Issuance of common stock upon exercise of options	—	—	78	—	—	—	—	—
Non-employee stock-based compensation expense	—	—	—	—	17	—	—	17
Employee and director stock-based compensation expense	—	—	—	—	866	—	—	866
Accretion to redemption value of redeemable convertible preferred stock	—	9,289	—	—	—	—	(9,289)	(9,289)
Repurchase of convertible preferred stock	(39,606)	(8,250)	—	—	8,247	—	—	8,247
Conversion of preferred stock to common stock	(621,453)	(319,736)	2,793,281	—	319,736	—	—	319,736
Issuance of common stock, net of $5,356 issuance costs	—	—	6,030,969	1	20,711	—	—	20,712
Extinguishment of debt through issuance of common stock	—	—	624,944	—	16,945	—	—	16,945
Net loss	—	—	—	—		—	(10,073)	(10,073)
Net unrealized gain on marketable securities	—	—	—	—	—	2	—	2

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balances as of December 31, 2013	—	$ —	9,455,064	$ 1	$ 367,435	$ 2	$ (348,842)	$ 18,596
Issuance of common stock upon exercise of warrants	—	—	36,613	—	595	—	—	595
Issuance of common stock upon exercise of employee stock options	—	—	431	—	4	—	—	4
Non-employee stock-based compensation expense	—	—	—	—	8	—	—	8
Employee and director stock-based compensation expense	—	—	—	—	1,173	—	—	1,173
Conversion of incentive award from liability to equity accounting	—	—	—	—	121	—	—	121
Issuance of common stock, net of $3,034 issuance costs	—	—	5,204,000	—	25,286	—	—	25,286
Net loss			—	—	—	—	(31,917)	(31,917)
Net unrealized loss on marketable securities	—	—	—	—	—	(16)	—	(16)
Balances as of December 31, 2014	—	$ —	14,696,108	$ 1	$ 394,622	$ (14)	$ (380,759)	$ 13,850

See accompanying notes.

CymaBay Therapeutics, Inc.
Statements of Cash Flows
(In Thousands)

	Year Ended December 31,	
	2014	2013
Operating activities		
Net loss	$ (31,917)	$ (10,073)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	18	55
Amortization of notes payable conversion option	—	10
Non-employee stock-based compensation expense	8	17
Employee and director stock-based compensation expense	1,284	875
Amortization of premium on marketable securities	453	48
Non-cash interest associated with debt discount accretion	198	47
Change in fair value of warrant liability	7,236	494
Loss (gain) on sale of property and equipment	2	(632)
Changes in assets and liabilities:		
Contract receivables	(101)	(2)
Accrued interest receivable	(68)	(59)
Prepaid expenses	(1,627)	(217)
Other assets	3	(216)
Accounts payable	1,388	40
Accrued liabilities	1,889	499
Accrued interest payable	107	692
Other liabilities	13	(36)
Net cash used in operating activities	(21,114)	(8,458)
Investing activities		
Purchases of property and equipment	(103)	—
Proceeds from sale of property and equipment	—	658
Purchases of marketable securities	(27,334)	(6,933)
Proceeds from sales and maturities of marketable securities	10,499	44
Net cash used in investing activities	(16,938)	(6,231)
Financing activities		
Proceeds from facility loan	—	4,853
Repayment of facility loan principal	(244)	—
Proceeds from issuance of common stock and warrants, net of issuance costs	25,430	26,514
Repurchase of preferred stock	—	(3)
Proceeds from issuance of common stock upon exercise of warrants	46	—
Proceeds from issuance of common stock upon exercise of employee stock options	5	—
Net cash provided by financing activities	25,237	31,364
Net (decrease) increase in cash and cash equivalents	(12,815)	16,675
Cash and cash equivalents at beginning of period	24,401	7,726
Cash and cash equivalents at end of period	$ 11,586	$ 24,401
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 435	$ 74
Financing costs in accrued expenses	—	309
Issuance of common stock warrants to lenders	443	479
Fair value of forward contract	—	453
Issuance of common stock warrants to common stockholders	—	5,493
Conversion of preferred shares into common stock	—	323,155
Issuance of common stock for debt extinguishment	—	16,945
Issuance of common stock upon warrant exercises	549	—
Noncash issuance costs incurred in common stock financing	453	—
Reclassification of incentive awards to equity	121	—

See accompanying notes.

NOTES TO FINANCIAL STATEMENTS

1. Organization and Description of Business

CymaBay Therapeutics, Inc. (the "Company") is focused on developing therapies to treat metabolic diseases with high unmet medical need, including serious rare and orphan disorders. Arhalofenate, the Company's lead product candidate, is being developed for the treatment of gout. Arhalofenate has successfully completed five Phase 2 clinical trials in patients with gout and consistently demonstrated the ability to reduce gout flares and reduce serum uric acid (sUA). Gout flares are recurring and painful episodes of joint inflammation that are triggered by the presence of monosodium urate crystals that form as a result of elevated sUA levels. The Company believes the potential for arhalofenate to prevent or reduce flares while also lowering sUA could differentiate it from currently available treatments for gout and classify it as the first potential drug in what the Company believes could be a new class of gout therapy referred to as Urate Lowering Anti-Flare Therapy (ULAFT). Arhalofenate has established a favorable safety profile in clinical trials involving over 1,000 patients exposed to date. The Company is currently planning to hold an end of phase 2 meeting with the FDA in the second half of 2015 to review the results of its completed studies and to discuss the design of a phase 3 program for arhalofenate. Our second product candidate, MBX-8025, demonstrated favorable effects on cholesterol, triglycerides and markers of liver health in a Phase 2 clinical trial in patients with mixed dyslipidemia. The Company is planning to purse development of MBX-8025 in a number of orphan diseases in which these attributes could be beneficial, such as homozygous familial hypercholestorolemia (HoFH), primary biliary cirrhosis (PBC) and severe hypertriglyceridemia (SHTG). The Company also believes that MBX-8025 could have utility in the treatment of the more prevalent, but high unmet need, indication of nonalcoholic steatohepatitis (NASH). The Company plans to initiate one or more pilot or proof-of-concept studies for MBX-8025, beginning with HoFH, in the first half of 2015.

The Company is an emerging growth company. Under the JOBS Act emerging growth companies can delay adopting new or revised accounting standards until such time of those standards apply to private companies. The Company has adopted this exemption from new or revised accounting standards, and therefore, it may not be subject to the same new or revised accounting standards as other public companies that are not "emerging growth companies."

Liquidity

The accompanying financial statements for the years ended December 31, 2014 and 2013, have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business for the foreseeable future. The Company has incurred net losses from operations since its inception and has an accumulated deficit of $380.8 million as of December 31, 2014. The Company recorded net losses of $31.9 million and $10.1 million for the years ended December 31, 2014 and 2013, respectively. The Company also recorded negative cash flows from operating activities during 2014 and 2013 of $21.1 million and $8.5 million, respectively. To date, none of the Company's product candidates have been approved for marketing and sale, and the Company has not recorded any product sales. Management expects operating losses to continue for the next several years. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses or whether or when we will become profitable, if at all. Our research and development expenditures and general and administrative expenses have exceeded our revenues for each year, and we expect to spend significant additional amounts to fund the continued development of our candidates. As a result, we expect to continue to incur substantial operating expenses, and, consequently, we will need to generate significant additional revenues to achieve future profitability.

The Company's ability to achieve profitability is dependent primarily on its ability to successfully develop, acquire or in-license additional product candidates, continue clinical trials for product candidates currently in clinical development, obtain regulatory approvals, and support commercialization activities for partnered product

candidates. Products developed by the Company will require approval of the U.S. Food and Drug Administration (FDA) or a foreign regulatory authority prior to commercial sale. The regulatory approval process is expensive, time-consuming, and uncertain, and any denial or delay of approval could have a material adverse effect on the Company. Even if approved, the Company's products may not achieve market acceptance and will face competition from both generic and branded pharmaceutical products.

In 2013, in order to address immediate capital requirements, the Company entered into a series of financing transactions. Specifically, on September 30, 2013, all of the shares of the Company's outstanding redeemable convertible preferred stock converted to common stock and the Company issued shares of common stock and warrants to purchase shares of common stock in a private placement for gross proceeds of $26.8 million. The Company raised an additional $5.0 million in venture debt financing pursuant to a $10.0 million loan agreement, resulting in aggregate net proceeds to CymaBay of $28.8 million after deducting placement agent fees and offering expenses. Also on September 30, 2013, the Company issued shares of common stock in cancellation of approximately $16.9 million of debt owed to the lender. On October 31, 2013, the Company sold additional shares of common stock and warrants to purchase shares of common stock, which sales are also part of the private placement, for net proceeds to CymaBay of $2.2 million after deducting placement agent fees and estimated offering expenses. Further, on November 22, 2013, the Company entered into an agreement with investors to purchase shares of common stock and warrants to purchase shares of common stock as part of the private placement for net proceeds of $2.7 million, which sales occurred shortly after the listing of the Company's common stock on the over-the-counter market on January 24, 2014. Collectively, the private placement, the venture debt financing and the issuance of our common stock in cancellation of the $16.9 million of debt is referred to as the 2013 financing. Furthermore, on July 25, 2014, the Company completed a public offering of 4.6 million shares of our common stock at $5.50 per share which the Company refers to as the 2014 public offering. Net proceeds to the Company in connection with the 2014 public offering were approximately $23.0 million after deducting underwriting discounts, commissions and offering expenses.

The Company has incurred operating losses since its inception and had an accumulated deficit of $380.8 million at December 31, 2014. Management expects operating losses and negative cash flows to continue for the foreseeable future. As of December 31, 2014, the Company had $34.8 million in cash and cash equivalents and marketable securities, which is available to fund future operations. Taking into account the repayment of its outstanding debt classified within current liabilities on the Company's Balance Sheet as of December 31, 2014, the Company anticipates that it will be required to seek additional equity or debt financing and/or non-dilutive funding from potential licensing deals to fund its operations through December 31, 2015. If the Company is unable to obtain additional funding during 2015, the Company will delay one or more of its planned development programs commencing early in the second half of 2015. Consistent with the actions the Company has taken in the past, it will prioritize necessary and appropriate steps to enable the continued operations of the business and preservation of the value of its assets beyond the next twelve months, including but not limited to actions such as reduced personnel-related costs, additional curtailment of the Company's development activities and other discretionary expenditures that are within the Company's control. These reductions in expenditures, if required, may have an adverse impact on the Company's ability to achieve certain planned objectives during 2015. In addition to seeking equity or debt financing, the Company may seek to access additional capital to support future operations through licensing, partnering or other strategic collaborative arrangements. It is unclear if or when any such transactions will occur, on satisfactory terms or at all.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The 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 financial statements and accompanying notes. Accounting estimates and assumptions are inherently uncertain. Management bases its estimates on historical experience and on assumptions believed to be reasonable under the circumstances. The estimation

process often may yield a range of potentially reasonable estimates of the ultimate future outcomes, and management must select an amount that falls within that range of reasonable estimates. Actual results could differ materially from those estimates and assumptions. The Company believes significant judgment is involved in determining and in estimating the valuation of stock-based compensation, accrued clinical trial expenses, and equity instrument valuations. 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 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 consist of cash and cash equivalents, short-term marketable securities, accounts payable, accrued expenses, warrant liabilities, and forward contracts. Fair value estimates of these instruments are made at a specific point in time, based on relevant market information. These estimates may be subjective in nature and involve uncertainties and matters of significant judgment and therefore cannot be determined with precision. The carrying amounts of cash and cash equivalents, accounts payable and accrued expenses are generally considered to be representative of their respective fair values because of the short-term nature of those instruments.

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

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

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

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

The following table presents the fair value of the Company's financial assets and liabilities using the above input categories (in thousands):

(In thousands)	As of December 31, 2014			
Description	**Level 1**	**Level 2**	**Level 3**	**Fair Value**
Money market funds	$9,941	$ —	$ —	$ 9,941
Corporate debt and asset backed securities	—	23,209	—	23,209
Total assets measured at fair value	$9,941	$23,209	$ —	$ 33,150
Warrant liability	$ —	$ —	$13,596	$ 13,596
Total liabilities measured at fair value	$ —	$ —	$13,596	$ 13,596

Description	As of December 31, 2013			
	Level 1	Level 2	Level 3	Fair Value
Money market funds	$21,097	$ —	$ —	$ 21,097
Corporate debt and asset backed securities	—	6,843	—	6,843
Total assets measured at fair value	$21,097	$6,843	$ —	$ 27,940
Forward contract	$ —	$ —	$ 453	$ 453
Warrant liability	—	—	6,466	6,466
Total liabilities measured at fair value	$ —	$ —	$6,919	$ 6,919

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

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

The following table sets forth a summary of the changes in the fair value of our Level 3 financial instruments (in thousands):

	Warrant Liability	Forward Contract
Balance as of December 31, 2013	$ 6,466	$ 453
Issuance of financial instrument	443	—
Change in fair value	7,236	(10)
Settlement of financial instrument	(549)	(443)
Balance as of December 31, 2014	$13,596	$ —

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

Cash, Cash Equivalents, and Marketable Securities

The Company considers all highly liquid investments with a remaining maturity of 90 days or less at the time of purchase to be cash equivalents. Cash and cash equivalents consist of deposits with commercial banks in checking, interest-bearing, and demand money market accounts. The Company invests excess cash in marketable securities with high credit ratings which are classified in Level 1 and Level 2 of the fair value hierarchy. These securities consist primarily of corporate debt and asset-backed securities and are classified as "available-for-sale." Management may liquidate any of these investments in order to meet the Company's liquidity needs in the next year. Accordingly, any investments with accompanying contractual maturities greater than one year from the balance sheet date are classified as short-term in the balance sheet.

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

Restricted Cash

The Company is required to maintain compensating cash balances with financial institutions that provide the Company with its corporate credit cards. As of December 31, 2014 and 2013, cash restricted under these arrangements was $100,000 and $155,000, respectively. These amounts are presented in other assets on the accompanying balance sheets.

Concentration of Credit Risk

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

Contract Receivables

Contract receivables consist of amounts due from a collaboration partner for certain reimbursable patent costs. Such expense reimbursements are presented as a reduction to general and administrative expense in the Company's Statements of Operations and Comprehensive Loss.

Property and Equipment

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

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss is

recognized if the estimated undiscounted future cash flow expected to result from the use and eventual disposition of an asset is less than the carrying amount. While the Company's current and historical operating losses and cash flows are indicators of impairment, the Company believes the future cash flows to be received support the carrying value of its long-lived assets. Accordingly, the Company has not recognized any impairment losses as of December 31, 2014 and 2013.

Deferred Rent

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

Research and Development Expenses

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

The expenses related to clinical trials are based upon estimates of the services received and efforts expended pursuant to contracts with research institutions and clinical research organizations (CROs) that conduct and manage clinical trials on behalf of the Company. The Company's objective is to reflect the appropriate trial expenses in its financial statements by matching those expenses with the period in which services and efforts are incurred. Expenses related to clinical trials are accrued based upon the level of activity incurred under each contract as indicated by such factors as progress made against specified milestones or targets in each period, patient enrollment levels, and other trial activities as reported by CROs. Accordingly, the Company's clinical trial accrual is dependent upon the timely and accurate reporting of expenses by clinical research organizations and other third-party vendors. Payments made to third parties under these clinical trial arrangements in advance of the receipt of the related services are recorded as prepaid assets, depending on the terms of the agreement, until the services are rendered. We base our estimates on the best information available at the time. However, additional information may become available to us which may allow us to make a more accurate estimate in future periods. In this event, we may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain. Such increases or decreases in cost are generally considered to be changes in estimates and will be reflected in research and development expenses in the period first identified.

Stock-Based Compensation

Employee and director stock-based compensation is measured at the grant date, based on the fair-value-based measurements of the stock awards, and the portion that is ultimately expected to vest is recognized as an expense over the related vesting periods, net of estimated forfeitures. The Company calculates the fair-value-based measurements of options using the Black-Scholes valuation model and recognizes expense using the straight-line attribution method.

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

Common Stock Warrants

The Company's outstanding common stock warrants issued in connection with the 2013 financing are classified as liabilities in the accompanying balance sheets as they contain provisions that could require the Company to settle the warrants in cash. The warrants were recorded at fair value using either the Black-Scholes option pricing model, or a probability weighted expected return model or a binomial model, depending on the characteristics of the warrants. The fair value of these warrants is re-measured at each financial reporting period with any changes in fair value being recognized as a component of other income (expense) in the accompanying statements of operations and comprehensive loss.

Income Taxes

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

The accounting guidance for uncertainty in income taxes prescribes a recognition threshold and measurement attribute criteria for the financial recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination based on the technical merits of the position.

The Company records interest related to income taxes, if any, as interest, and any penalties would be recorded as other expense in the statements of operations and comprehensive loss. There was no interest or penalties related to income taxes recorded during the years ended December 31, 2014 and 2013.

Comprehensive Loss

Comprehensive loss includes net loss and net unrealized gains and losses on marketable securities, which are presented in a single continuous statement. Comprehensive loss is disclosed in the statements of convertible preferred stock and stockholders' deficit, and is stated net of related tax effects, if any.

Net Income (Loss) Per Common Share

Basic net income (loss) per share of common stock is based on the weighted average number of shares of common stock outstanding equivalents during the period. Prior to the 2013 financing, in addition to common stock, the Company had redeemable convertible preferred stock outstanding that contractually entitled the holder to participate in dividends and earnings of the Company. Accordingly, the Company applied the two-class method for calculating net income (loss) per share. Under this method, all undistributed earnings were allocated first to the preferred stockholders based on their contractual right to dividends. This right was calculated on a pro rated basis for the portion of the period the preferred shares were outstanding. In addition, in connection with the 2013 financing, during the year ended December 31, 2013, the Company converted all outstanding redeemable convertible preferred stock into common stock. The excess of the carrying amount of such redeemable convertible preferred stock over the fair value of the consideration paid to the holders was treated as an adjustment that reduced preferred stockholders' dividend or distribution entitlement. The amount of earnings that resulted from adjusting net loss for the period as described above was allocated between weighted average number of participating preferred and common stock shares based on their entitlement to such distributions as if all of the earnings of the period had been distributed.

Diluted net loss per share of common stock is calculated using the more dilutive of the two approaches: one, "as-converted" method, under which the weighted average number of common stock shares outstanding during the period is adjusted to include the assumed conversion of redeemable convertible preferred stock at the beginning of the period, and the other, the "two-class" method as described above. Under either approach, the weighted average number of shares outstanding is also adjusted to include the assumed exercises of stock options and warrants, if dilutive. For periods in which the Company has basic net loss per share of common stock, such as for the year ended December 31, 2014, diluted net loss per share is the same as basic, as any adjustments would have been anti-dilutive. For the year ending December 31, 2013, the Company's diluted net loss per common share was calculated using the "as-converted" method, as it resulted in a net loss per share of common stock and accordingly, was more dilutive than the "two-class" method.

In all periods presented, the Company's outstanding stock options and warrants were excluded from the calculation of earnings (loss) per share because the effect would be antidilutive.

The following table sets forth the computation of basic and diluted net income (loss) per share (in thousands, except share and per share amounts):

	Year Ended December 31,	
	2014	2013
Basic:		
Numerator:		
Net loss	$ (31,917)	$ (10,073)
Accretion to redemption value of redeemable convertible preferred stock	—	(9,289)
Reduction in redeemable convertible preferred stock distribution entitlement upon extinguishment	—	313,933
Amounts allocated to participating redeemable convertible preferred stock	—	(50,577)
Net (loss) income allocated to common stock—basic	$ (31,917)	$ 243,994
Denominator:		
Weighted average number of common stock shares outstanding—basic	12,048,985	2,357,036
Net (loss) income per share-basic:	$ (2.65)	$ 103.52
Diluted:		
Numerator:		
Net (loss) income allocated to common stock	$ (31,917)	$ 243,994
Adjustments from assumed conversion of redeemable convertible preferred stock	—	(254,067)
Net loss allocated to common stock—diluted	$ (31,917)	$ (10,073)
Denominator:		
Weighted average number of common stock shares outstanding	12,048,985	2,357,036
Weighted average number of preferred stock shares outstanding	—	488,573
Total common stock equivalent shares	12,048,985	2,845,609
Net loss per share—diluted	$ (2.65)	$ (3.54)

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

	Year Ended December 31,	
	2014	2013
Warrants for common stock	1,768	1,743
Common stock options	991	577
Incentive awards	247	—
	3,006	2,320

3. Marketable Securities

Marketable available-for-sale securities as of December 31, 2014 and 2013 consist of the following (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
As of December 31, 2014:				
Corporate debt securities	$ 19,706	$ 1	$ (14)	$ 19,693
Asset-backed securities	3,516	—	—	3,516
	$ 23,222	$ 1	$ (14)	$ 23,209

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
As of December 31, 2013:				
Corporate debt securities	$ 6,355	$ 3	$ (2)	$ 6,356
Asset-backed securities	486	1	—	487
	$ 6,841	$ 4	$ (2)	$ 6,843

As of December 31, 2014 and 2013, the Company's corporate debt marketable securities had contractual maturities of less than one year and asset-backed securities had contractual maturities between 2-5 years. Realized gains and losses were immaterial for the years ended December 31, 2014 and 2013. None of these investments have been in a continuous unrealized loss position for more than 12 months as of December 31, 2014 and 2013.

4. Certain Balance Sheet Items

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

	December 31,	
	2014	2013
Office and computer equipment	$ 176	$ 556
Purchased software	46	166
Furniture and fixtures	33	42
Leasehold improvements	66	2,534
Total	321	3,298
Less accumulated depreciation and amortization	(235)	(3,295)
Property and equipment, net	$ 86	$ 3

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2014	2013
Accrued compensation	$1,504	$ 518
Accrued pre-clinical and clinical trial expenses	1,732	418
Accrued professional fees	73	782
Forward contract	—	453
Other accruals	79	80
Total accrued liabilities	$3,388	$2,251

5. Collaboration and License Agreements

In June 2006, the Company entered into an exclusive worldwide, royalty-bearing license to MBX-8025 and certain other PPARδ compounds (the "PPARδ Products") with Janssen Pharmaceutical NV, with the right to grant sublicenses to third parties to make, use and sell such PPARδ Products. Under the terms of the agreement, the Company has full control and responsibility over the research, development and registration of any PPARδ Products and is required to use diligent efforts to conduct all such activities. Janssen has the sole responsibility for the preparation, filing, prosecution, maintenance of, and defense of the patents with respect to, the PPARδ Products. Janssen has a right of first negotiation under the agreement to license a particular PPARδ Product from the Company in the event that the Company elects to seek a third party corporate partner for the research, development, promotion, and/or commercialization of such PPARδ Products. Under the terms of the agreement Janssen is entitled to receive up to an 8% royalty on net sales of PPARδ Products. No payments were made and no royalties were received under this agreement during the years ended December 31, 2014 and 2013.

In June 2010, the Company entered into two development and license agreements with Janssen Pharmaceuticals, Inc. (Janssen), a subsidiary of Johnson and Johnson, to further develop and discover undisclosed metabolic disease target agonists for the treatment of T2DM and other disorders and received a one-time nonrefundable technology access fee related to the agreements. The Company is also eligible to receive up to $228 million in contingent payments if certain development and commercial events are achieved as well as royalties on worldwide net sales of products. No such payments have been made to date. Under the terms of the agreements, Janssen has full control and responsibility over the research, development and registration of any products developed and/or discovered from the metabolic disease targets and is required to use diligent efforts to conduct all such activities.

In June 1998, the Company entered into a license agreement with DiaTex, Inc. (DiaTex) relating to products containing halofenate, its enantiomers, derivatives, and analogs (the licensed products). The license agreement provides that DiaTex and the Company are joint owners of all of the patents and patent applications covering the licensed products and methods of producing or using such compounds, as well as certain other know-how (the covered IP). As part of the license agreement, the Company received an exclusive worldwide license, including as to DiaTex, to use the covered IP to develop and commercialize the licensed products. The Company also retained the right to sub-license the covered IP. The license agreement contains a $2,000 per month license fee as well as a requirement to make additional payments for development achievements and royalty payments on any sales of licensed products. Pursuant to the license agreement, all of the Company's patents and patent applications related to arhalofenate, its use, and production are jointly owned with DiaTex. DiaTex is entitled to up to $0.8 million for the future development of arhalofenate, as well as royalty payments on any sales of products containing arhalofenate. No development payments were made in the years ended December 31, 2014 and 2013 and no royalties have been paid to date.

6. Debt

JJDC Convertible Note

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

In February and July 2009, the Company issued notes in the aggregate amount of $7.0 million and $6.7 million, respectively, in accordance with the terms of the equity and loan facility with JJDC. The notes were due in February 2012 and July 2012, including interest that accrued at 4.42% per annum and 4.960% per annum, respectively. In January 2012, the Company amended the maturity dates of the outstanding $7.0 million and $6.7 million convertible promissory notes to extend the maturity date to March 1, 2013, and interest rates were increased to 4.919% and 5.46% per annum, respectively. In addition, the conversion price of the notes to convert into shares of the Company's Series C-1 Preferred Stock was decreased from $438.84 per share to $292.56 per share. All of these notes were further amended in March 2013, to extend the maturity date on the notes to August 1, 2013, and to make the notes subordinate to repayment of the Company's severance obligations to all employees until January 1, 2014. On July 31, 2013, the maturity date was extended to December 31, 2013. For the year ended December 31, 2013, the Company recognized $0.6 million of interest expense related to the convertible promissory notes. On September 30, 2013, the outstanding principal and accrued interest of $16.9 million under the equity and loan facility with JJDC was extinguished in exchange for the issuance of 624,944 shares of common stock as an integral part of the 2013 finance restructuring.

Facility Loan

On September 30, 2013, the Company entered into a facility loan agreement with Silicon Valley Bank and Oxford Finance for a total loan amount of $10.0 million of which the first tranche of $5.0 million was drawn as part of the 2013 financing and bears interest at a rate equal 8.75% per annum. The second tranche of $5.0 million became available to the Company upon its February 24, 2015 announcement of the achievement of positive Phase 2b data (the second draw milestone) and shall remain available to the Company until June 30, 2015. Loans under the second tranche will bear interest at a rate fixed at the time of borrowing equal to the greater of (i) 8.75% per annum and (ii) the sum of the Wall Street Journal prime rate plus 4.25% per annum.

For each tranche borrowed, the Company is required to make 12 monthly interest only payments after the funding date followed by a repayment schedule equal to 36 equal monthly payments of interest and principal. After the 36-month amortization period of each tranche, the remaining balance of such tranche and a final payment equal to 6.50% of the original principal amount of the applicable tranche are payable on the maturity date of such tranche. The final payment equal to 6.50% of the original principal is being accreted over the life of the loan.

Future principal payments due under the loan facility are as follows (in thousands):

	Principal Payments
Year ending December 31:	
2015	$ 1,546
2016	1,687
2017	1,522
Total future principal payments due under loan agreement	$ 4,755

During the loan term, the term loan facility provides that the Company must maintain compliance with one of two financial covenants at all times: (1) maintain 1.3 times cash to outstanding debt or (2) maintain sufficient cash on hand to support eight months of operations based on a trailing average monthly cash burn. The term loan facility also contains a series of performance covenants however failure to comply with these performance covenants shall not be an event of default under the term loan facility so long as the Company deposits an amount equal to 100% of the aggregate outstanding term loans in a segregated, blocked deposit account at Silicon Valley Bank. As of December 31, 2014, the Company was in compliance with its loan covenants.

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

The Company was required to pay a facility fee of 1.00% on the term loan facility commitment. In addition, at the time of the facility loan drawdown, the Company issued warrants exercisable for a total of 121,739 shares of the Company's common stock to the lenders at an exercise price of $5.00 per share. As a result of this a warrant liability of $0.5 million was recorded in the accompanying balance sheet as of September 30, 2013. The facility fee, the warrant value on its issuance date, and other debt issuance costs were reflected as a debt discount and are being amortized to interest expense over the term of the outstanding loan using the effective interest rate method. The liability classified warrants must be remeasured at fair value on each reporting date and changes in fair value are recorded as other income, net in the accompanying statement of operations and comprehensive loss.

7. Commitments and Contingencies

Operating Lease Commitments

For the year ended December 31, 2013, the Company leased office and laboratory space in a single building in Hayward, California. The facility lease, as amended on July 15, 2010, had a term of four years, unless terminated earlier by the Company, and expired on April 30, 2014. Rent expense was $0.4 million and $0.5 million for the years ended December 31, 2014 and 2013. On November 8, 2013, the Company entered into a new lease commencing January 16, 2014, and expiring on December 31, 2018, for 8,894 square feet of office space in Newark, California.

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

	Lease Payments
Year ending December 31:	
2015	$ 209
2016	216
2017	222
2018	228
Total future minimum payments	$ 875

Indemnification

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnification, including indemnification associated with product liability or infringement of intellectual property rights. The Company's exposure under these agreements is unknown because it involves future claims that may be made against the Company that may be, but

have not yet been, made. To date, the Company has not paid any claims or been required to defend any action related to these indemnification obligations, and no amounts have been accrued in the accompanying balance sheets related to these indemnification obligations.

The Company has agreed to indemnify its executive officers and directors for losses and costs incurred in connection with certain events or occurrences, including advancing money to cover certain costs, subject to certain limitations. The maximum potential amount of future payments the Company could be required to make under this indemnification is unlimited; however, the Company maintains insurance policies that may limit its exposure and may enable it to recover a portion of any future amounts paid. Assuming the applicability of coverage, the willingness of the insurer to assume coverage, and subject to certain retention, loss limits, and other policy provisions, the Company believes the fair value of these indemnification obligations is not material. Accordingly, the Company has not recognized any liabilities relating to these obligations as of December 31, 2014 and 2013. No assurances can be given that the covering insurers will not attempt to dispute the validity, applicability, or amount of coverage without expensive litigation against these insurers, in which case the Company may incur substantial liabilities as a result of these indemnification obligations.

8. Redeemable Convertible Preferred Stock

Upon the closing of the 2013 financing on September 30, 2013, all the outstanding shares of the Company's redeemable convertible preferred stock were converted into 2,793,281 shares of common stock, and the related carrying value of $320.0 million was reclassified to additional paid-in capital. As of December 31, 2014 and 2013, no shares of redeemable convertible preferred stock were issued or outstanding.

Prior to the September 30, 2013 conversion, the Company had the following series of outstanding convertible preferred stock (collectively, the Preferred Stock): Series A-1 Preferred, Series B-1 Preferred, Series C-1 Preferred, Series D-1 Preferred, Series E-1 Preferred and Series E-3 Preferred. Series E-1 Preferred and Series E-3 Preferred are collectively referred to as the Series E Preferred. The Preferred Stock was initially recorded at its original purchase price, which represented fair value on the date of issuance, net of issuance costs, if any. The original purchase price per share of Series A-1 Preferred, Series B-1 Preferred, Series C-1 Preferred, Series D-1 Preferred, and Series E Preferred was equal to $232.93, $232.93, $365.70, $232.94, and $232.93 per share, respectively. The preferred stock balances were recorded at the original fair value and the accreted dividends based on the per share terms at issuance of Series A-1 Preferred, Series B-1 Preferred, Series C-1 Preferred, Series D-1 Preferred, and Series E Preferred, which were equal to $18.64, $18.64, $29.26, $18.64, and $18.64 per share per annum, respectively.

The shares of Series B-1 Preferred, Series D-1 Preferred, and Series E Preferred were redeemable upon the request of the holders of at least 66 2/3% of outstanding shares of Series B-1 Preferred, voting as a separate class, and 51% of outstanding shares of Series D-1 Preferred and Series E Preferred, voting together as a separate class. In this event, the Company would have been required to redeem the shares in three equal annual installments, beginning in September 2021, at the applicable original purchase price per share. All shares of Preferred Stock were redeemable in the event of a change of control at their liquidation preferences.

As all Preferred Stock was redeemable either at the option of the holder or upon an event outside the control of the Company (i.e., a change in control), the related amounts have been presented outside of stockholders' equity (deficit). In August and December 2003, the Company completed two closings of a private placement of Series B-1 Preferred, in which the Company issued a total of 136,520 shares at a price of $232.93 per share for gross proceeds of $31.8 million. In November and December 2004, the Company completed two further closings of Series B-1 Preferred, in which the Company issued a total of 188,894 shares at a price of $232.93 per share for gross proceeds of $44.0 million. The Series B-1 Preferred investors in these two final closings also purchased warrants for 29,245 shares of common stock at an exercise price of $30.21 per share, with an exercise period of five years from the date of purchase, for $1.51 cents per share of common stock covered by the warrants. In November 2009, the exercise period of these warrants was extended to December 31, 2011. In December 2012,

the Company's Board of Directors reduced the number of shares exercisable under these warrant by 45% of the original shares and approved the extension of the exercise period until April 1, 2013. As of December 31, 2012, warrants to purchase 13,160 shares of common stock were outstanding. In April 2013, these warrants expired in accordance with their terms.

In August 2006, the Company issued 27,345 shares of Series C-1 Preferred to JJDC at a price of $365.70 per share, for gross proceeds of $10.0 million.

In April 2007, the Company issued 137,592 shares of Series D-1 Preferred at a price of $232.94 per share, for gross proceeds of $32.0 million. In connection with the issuance, the Series D-1 Preferred investors also purchased warrants for an aggregate of 20,639 shares of common stock at an exercise price of $22.13 per share, with an exercise period of five years from the date of purchase, for $0.79 cents per share of common stock covered by the warrants.

In August 2008, the Company repurchased 646, 1,610 and 472 shares of Series A-1 Preferred, Series B-1 Preferred and Series D-1 Preferred, respectively, and a warrant for 71 shares of common stock, for an aggregate purchase price of $82,000. The Company allocated the purchase price among the preferred shares and warrant based upon their respective fair values.

In November 2009, the Company issued 1,288 shares of Series E-1 Preferred upon the conversion of debt issued under a loan agreement. In June and December 2010, the Company issued 859 and 37,119 shares of Series E-1 Preferred, respectively, upon conversion of debt issued under a loan agreement.

In December 2010, the Company issued 71,543 shares of Series E-3 Preferred upon conversion of the JJDC convertible notes that were due in 2011.

The significant rights, privileges and preferences of the Preferred Stock were as follows:

Election of Directors

Prior to the September 30, 2013 conversion, the holders of Series B-1 Preferred were entitled to elect five members of the Company's Board of Directors, the holders of Series D-1 Preferred were entitled to elect one member of the Company's Board of Directors, and the holders of common stock were entitled to elect one member of the Company's Board of Directors, subject to certain restrictions. All remaining members of the Company's Board of Directors were elected by all of the stockholders voting on an as-if-converted basis.

Voting Rights

Prior to the September 30, 2013 conversion, the Preferred Stock carried voting rights equal to the number of shares of common stock into which it could be converted. Additionally, certain corporate actions could only be exercised upon the approval of holders of 66 2/3% of the outstanding shares of Series B-1 Preferred and Series C-1 Preferred, voting together as a single class, and 51% of the outstanding shares of Series D-1 Preferred and Series E Preferred, voting together as a single class.

Dividends

All dividends were payable when and if declared by the Company's Board of Directors. The holders of Series E Preferred were entitled to cumulative dividends in preference to the holders of Series A-1 Preferred, Series B-1 Preferred, Series C-1 Preferred, Series D-1 Preferred, and common stock. The holders of Series D-1 Preferred were entitled to cumulative dividends in preference to the holders of Series A-1 Preferred, Series B-1 Preferred, Series C-1 Preferred, and common stock. The holders of Series B-1 Preferred and Series C-1 Preferred were entitled to cumulative dividends in preference to the holders of Series A-1 Preferred and common stock.

The holders of Series A-1 Preferred were entitled to cumulative dividends in preference to the holders of common stock. The dividend rate was $18.64, $18.64, $29.26, $18.64, and $18.64 per annum for each outstanding share of Series E Preferred, Series D-1 Preferred, Series C-1 Preferred, Series B-1 Preferred, and Series A-1 Preferred, respectively. Additionally, if dividends were paid to any holder of common stock, the holders of Preferred Stock would receive a dividend of a per share amount (on an as-if-converted to common stock basis) equal to the amount paid to the holders of common stock.

Prior to the conversion of the Preferred Stock in connection with the 2013 financing, no dividends were declared and the aggregate cumulative dividends as of September 30, 2013, were $3.4 million ($47.28 per share), $1.9 million ($48.14 per share), $15.9 million ($116.00 per share), $5.6 million ($201.83 per share), $63.1 million ($168.96 per share), and $2.3 million ($183.64 per share) for Series E-3 Preferred, Series E-1 Preferred, Series D-1 Preferred, Series C-1 Preferred, Series B-1 Preferred, and Series A-1 Preferred, respectively. The aggregate cumulative dividends as of December 31, 2012, were $2.7 million ($38.04 per share), 1.5 million ($38.90 per share), $14.6 million ($106.75 per share), $5.1 million ($187.32 per share), $59.6 million ($159.72 per share), and $2.2 million ($174.40 per share) for Series E-3 Preferred, Series E-1 Preferred, Series D-1 Preferred, Series C-1 Preferred, Series B-1 Preferred, and Series A-1 Preferred, respectively.

Liquidation Preference

While the Preferred Stock was outstanding, in the event of a liquidation, dissolution, winding up, or change in control of the Company, the liquidation preference of each stockholder class was to be paid in the following order, from available funds: first to the holders of Series E-1 Preferred and Series E-3 Preferred, second to the holders of Series D-1 Preferred, third to the holders of Series B-1 Preferred and Series C-1 Preferred, and fourth to the holders of Series A-1 Preferred. After payment of the Preferred Stock liquidation preferences, the remaining assets of the Company were to be distributed ratably to all holders of common stock and Preferred Stock on an as-if-converted basis. The liquidation preference of Series E-1 Preferred, Series E-3 Preferred, Series D-1 Preferred, Series C-1 Preferred, Series B-1 Preferred, and Series A-1 Preferred was equal to $465.87, $290.97, $232.93, $365.70, $232.93, and $232.93 per share, respectively, plus any cumulative unpaid dividends. If there were insufficient funds available to satisfy each liquidation preference in its entirety, the holders of Preferred Stock were to be paid a pro rata amount based on their liquidation preference.

Conversion Rights

Each share of Preferred Stock was convertible at any time, at the option of the holder, into shares of the Company's common stock at then applicable conversion rate. The conversion rate for each of the series of Preferred Stock was 1:1, except for the Series D-1 Preferred, which had a conversion rate of 1.365:1. With respect to the Series E Preferred, Series D-1 Preferred, Series B-1 Preferred, and Series A-1 Preferred, if the Company issued common stock or securities convertible into or exercisable for shares of common stock at a price less than the respective original purchase price per share, the conversion rate of such stock was to be adjusted to the lowest price per share paid in such issuance. The conversion rate for Preferred Stock would not be adjusted for common stock issuances on the exercise of options or warrants issued to employees, directors, or consultants of the Company and in certain other circumstances.

Each share of Preferred Stock automatically converted into common stock upon the approval of holders of 66 2/3% of the outstanding shares of Series B-1 Preferred, voting as a separate class, and 51% of the outstanding shares of Series D-1 Preferred and Series E Preferred, voting together as a separate class, or upon the closing of an underwritten public offering of the Company's common stock pursuant to an effective registration statement under the Securities Act of 1933, as amended, at a per share price of at least $8.00, and raising aggregate gross proceeds of at least $30.0 million. In connection with the 2013 financing each holder of the Company's preferred stock that participated in the 2013 financing for between 1% and up to 99% of such holders "*Pro Rata Share*" (as defined in the Company's then effective certificate of incorporation) had each share of preferred stock represented by such participation amount converted into four shares of common stock and the balance of any

shares of preferred stock converted at the then applicable conversion rate. Any holder that participated in the 2013 financing for between 100% and 300% of such holder's Pro Rata Share (the "*Participation Multiple*") had each share of preferred stock convert into shares of common stock by multiplying the product of (y) the aggregate number of shares of preferred stock held by such holder multiplied by the applicable Participation Multiple and (z) four (4).

9. Common Stock

The Company was authorized to issue 100,000,000 shares of common stock as of December 31, 2014 and 2013, respectively.

Common Stock Issuances

On September 30, 2013, all the outstanding shares of the Company's redeemable convertible preferred stock were converted into 2,793,281 shares of common stock and the related carrying value of $320.0 million was reclassified to additional paid-in capital.

Commencing on September 30, 2013, the Company entered into a series of financing transactions (collectively referred to as the 2013 financing) which resulted in the issuance of common stock and warrants to purchase shares of common stock. Specifically, on September 30, 2013, the Company sold 5,366,669 shares of common stock and 1,073,338 warrants to purchase shares of common stock in a private placement for net proceeds to CymaBay of $22.8 million after deducting placement agent fees and estimated offering expenses. Also on that date, the Company issued 624,944 shares of common stock in cancellation of approximately $16.9 million of debt owed to JJDC, the holder of that debt (Note 6).

On October 31, 2013, the Company sold an additional 664,300 shares of common stock and warrants to purchase 132,860 shares of common stock, which sales were also part of the private placement, for net proceeds to CymaBay of $2.2 million after deducting placement agent fees and estimated offering expenses.

On November 22, 2013, the Company entered into an agreement with investors to purchase 604,000 shares of common stock and 120,800 warrants to purchase shares of common stock as part of the private placement for net proceeds of $2.7 million, which sales were set to occur shortly after the listing of the Company's common stock on the over-the-counter market. Cymabay began trading on the over-the-counter market on January 24, 2014 enabling this portion of the financing to be completed in late January 2014.

On July 25, 2014, the Company completed a public offering of 4,600,000 shares of common stock at $5.50 per share, which the Company refers to as the 2014 public offering. Net proceeds to the Company in connection with the 2014 public offering were approximately $23.0 million after deducting underwriting discounts, commissions and offering expenses.

On November 7, 2014, we filed a $100 million registration statement on Form S-3 with the SEC and also entered into an at-the-market facility (ATM) to sell up to $25 million of common stock under the registration statement. As of December 31, 2014, no shares of common stock had been sold under this facility.

Common Stock Warrants

In connection with 2013 financing and the Company's private placement of common stock and warrants, in September 2013, October 2013 and January 2014, the Company issued five-year warrants to purchase 1,741,788 shares of CymaBay's common stock at an exercise price of $5.75 per share which the Company refers to here as the 2013 financing warrants. The Company also issued five-year warrants to purchase 121,739 shares of CymaBay's common stock to its lenders at an exercise price of $5.00 per share. The 2013 financing warrants contain provisions that are contingent on the occurrence of a change in control, which would conditionally

obligate the Company to repurchase the warrants for cash in an amount equal to their fair value using the Black-Scholes Option Pricing Model (the "Black-Scholes Model") on the date of such change in control. Due to these provisions, the Company is required to account for the 2013 financing warrants issued in September 2013, October 2013 and January 2014 and the lender warrants as a liability at fair value. In addition, the estimated liability related to these warrants is required to be revalued at each reporting period until the earlier of the exercise of the warrants, at which time the liability will be reclassified to stockholders' equity, or expiration of the warrants. These warrants were recorded at fair value upon issuance and were revalued at fair value as of December 31, 2014 and 2013 using a binomial lattice model and the resulting increases in fair value of $7.2 million and $0.5 million were recorded as an increase to the warrant liability and as a loss in other income (expense), net in the Company's Statement of Operations and Comprehensive Loss.

In November 2009, the Company's Board of Directors approved the extension of the time period in which the holders of warrants to purchase 29,245 shares of common stock are able to exercise their warrants that were issued in connection with the issuance of Series B-1 Preferred. The exercise periods of the warrants that originally ended in November 2009 were extended to December 31, 2010. In December 2010, the Company's Board of Directors further modified these warrants. The number of common shares exercisable under the warrants was reduced by 50% to 14,623, and the exercise period was extended to December 31, 2012. In December 2012, the Company's Board of Directors again modified these warrants to purchase common stock. The number of shares exercisable under the warrants issued with the issuance of the Series B-1 Preferred was reduced by 45% of the original shares to 13,163, and the exercise period was extended to April 1, 2013. The extension of the agreement did not cause a material change in value. In April 2013, these warrants expired.

In December 2010, the Company's Board of Directors modified the warrants to purchase common stock that were issued in connection with the issuance of Series D-1 Preferred. The exercise period of the warrants issued in connection with the Series D-1 Preferred issuance was extended to April 13, 2013. The charge related to the modifications to these warrants of $0.1 million was recorded to accumulated deficit and was determined using the Black-Scholes valuation model, with the following inputs used to determine the charge related to the modification: fair value of the Company's common stock of $15.90 per share, expected life of the modified warrants of one to two years, risk-free interest rate of 0.50%, and expected common stock price volatility of 83%. In April 2013, these warrants expired.

Shares of Common Stock Authorized for Issuance

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

	December 31, 2014	December 31, 2013
Common stock warrants	1,768,347	1,742,727
Equity incentive plans	1,549,616	577,294
Total reserved shares of common stock	3,317,963	2,320,021

10. Stock Plans and Stock-Based Compensation

Stock Plans

In September 2013, the Company's stockholders approved the 2013 Equity Incentive Plan ("2013 Plan"), under which shares of common stock are reserved for the granting of options, stock bonuses, and restricted stock awards by the Company. These awards may be granted to employees, members of the Board of Directors, and consultants to the Company. The 2013 Plan has a term of ten years and replaced the 2003 Equity Incentive Plan, which had similar terms. The 2013 Plan permits the Company to (i) grant incentive stock options to directors and employees at not less than 100% of the fair value of common stock on the date of grant; (ii) grant nonqualified

options to employees, directors, and consultants at not less than 85% of fair value; (iii) award stock bonuses; and (iv) grant rights to acquire restricted stock at not less than 85% of fair value. Options generally vest over a four- or five-year period and have a term of ten years. Options granted to 10% stockholders have a maximum term of five years and require an exercise price equal to at least 110% of the fair value on the date of grant. The exercise price of all options granted to date has been at least equal to the fair value of common stock on the date of grant. The share reserve under the 2013 Plan will automatically increase on January 1st of each year, for a period of not more than ten years, in an amount equal to 5% of the total number of shares of capital stock outstanding on December 31st of the preceding calendar year, unless the Board determines otherwise prior to December 31st of such calendar year. In June 2014, the Company's stockholders approved a proposal to increase the share reserve by an additional 500,000 shares.

Stock Plan Activity

In December 2013, the Company's Board of Directors modified the terms of 60,847 stock options held by employees, directors, and scientific advisors. Specifically, the exercise price for such options was reduced to $5, the fair market value of the Company's common stock on the date of modification, and the term of each option was extended to 10 years from the date of the modification. The Company accounted for this stock option modification by recognizing any unamortized expense related to the original unmodified options as of the modification date over the remaining vesting periods of those awards. The incremental expense resulting from this modification of $0.2 million was also recognized over the remaining vesting period. As substantially all of the modified awards were fully vested on the modification date, the Company recognized $0.2 million of noncash stock-based compensation expense related to this stock option modification in December 2013.

As of December 31, 2014, there were 311,300 shares available for issuance under the 2013 Plan. In accordance with the provisions of the 2013 Plan, the number of shares available for issuance under the plan automatically increased by 734,805 shares on January 1, 2015.

The following table summarizes stock option activity:

	Shares Subject to Outstanding Options	Weighted-Average Exercise Price of Options	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2013	577,253	$ 7.00	9.57	$ 3
Options granted	445,950	5.44		
Options exercised	(431)	4.82		
Options forfeited	(13,264)	4.99		
Options expired	(18,498)	19.39		
Outstanding as of December 31, 2014	991,010	$ 6.09	8.91	$ 4,559
Vested and expected to vest as of December 31, 2014	969,087	$ 6.11	8.90	$ 4,466
Exercisable as of December 31, 2014	515,908	$ 6.72	8.79	$ 2,461

The following table summarizes information about stock options outstanding as of December 31, 2014:

	Options Outstanding		Options Exercisable
Exercise Price	Number of Shares	Weighted-Average Remaining Contractual Term (Years)	Number of Shares
$4.77	10,983	7.07	9,538
$5.00	867,782	8.94	499,625
$5.23	10,000	9.65	—
$6.85	12,000	9.73	—
$7.00	77,000	9.28	—
$7.99	6,500	9.36	—
$30.21	3,290	0.02	3,290
$238.50	3,455	1.73	3,455
	991,010	8.91	515,908

Grant Date Fair Value

The following table presents the weighted-average assumptions the Company used with the Black-Scholes valuation model to derive the grant date fair value-based measurements of employee and director stock options and the resulting estimated weighted-average grant date fair-value-based measurements per share:

	Year Ended December 31,	
	2014	2013
Weighted-average assumptions:		
Expected term	6 yrs	6 yrs
Expected volatility	90%	92%
Risk-free interest rate	2.02%	1.76%
Expected dividend yield	0%	0%
Weighted-average grant date fair value per share	$ 4.06	$ 3.76

Expected Term

The Company does not believe it can currently place reliance on its historical exercise and post-vesting termination activity to provide accurate data for estimating the expected term. Therefore, for stock option grants made during the years ended December 31, 2014 and 2013, the Company has opted to use the simplified method for estimating the expected term which is an average of the contractual term of the options and its ordinary vesting period. The expected term represents the period of time that options are expected to be outstanding.

Expected Volatility

As the Company has limited trading history for its common stock, the expected stock price volatility for the Company's common stock was estimated by considering the volatility rates of similar publicly traded peer entities within the life sciences industry.

Risk-Free Interest Rate

The risk-free interest rate assumption was based on U.S. Treasury instruments with constant maturities whose term was consistent with the expected term of stock options granted by the Company.

Expected Dividend Yield

The Company has never declared or paid cash dividends and does not plan to pay cash dividends in the foreseeable future. Consequently, the Company uses an expected dividend yield of zero.

Common Stock Fair Value

Prior to the listing of the Company's common stock on a public exchange in January 2014, the Company's Board of Directors historically determined the fair value of the Company's common stock for the purpose of pricing the Company's equity awards to employees, directors, and consultants. The Company's Board of Directors, in making such fair value determinations, considered a number of factors, including the price at which Preferred Stock was issued to outside investors in arm's-length transactions, the rights, preferences, and privileges of the Preferred Stock relative to the common stock, important developments relating to advancement of the Company's technology and clinical programs, the Company's stage of development and business strategy, the likelihood of achieving a liquidity event for the shares of common stock, such as an initial public offering or sale of the Company, prevailing market conditions, and the market prices of various publicly held life sciences companies. Additionally, the Board of Directors considered contemporaneous valuations provided by third-party valuation specialists.

Forfeitures

The Company estimates forfeitures at the time of grant and revises these estimates in subsequent periods if actual forfeitures differ from those estimates. Changes in forfeiture estimates impact compensation in the period in which the change occurs.

The total intrinsic value of options exercised was not material for the years ended December 31, 2014 and 2013.

Vested and Unvested Awards

The total fair value of options vested for the years ended December 31, 2014 and 2013, was $1.0 million and $0.9 million, respectively.

As of December 31, 2014, and 2013 the total compensation expense related to unvested employee stock options to be recognized in future periods, excluding estimated forfeitures, was $1.9 million and $1.2 million, respectively. The weighted-average periods over which this compensation expense is expected to be recognized are 3.0 years and 3.9 years as of December 31, 2014 and 2013, respectively.

Incentive Awards

In December 2013, January 2014, and April 2014, as permitted by the 2013 Plan, the Company issued certain incentive awards to directors, employees and a consultant which are subject to 252,752 shares of the Company's common stock and are exercisable at a weighted average price of $5.21 per share when vested. The Company may determine at its option whether to settle exercised awards in shares of common stock or in cash. Each recipient's incentive award defines the number of common shares that may be acquired upon exercise provided the Company chooses to settle in shares. For awards settled in cash, the Company must pay the recipient the excess of the fair market value of the Company's common stock on the date of exercise over the exercise price paid by the recipient multiplied by the number of shares the recipient would be entitled to receive had the award been settled in shares of the Company's common stock.

Pursuant to their terms, the incentive awards will vest 100% on the second anniversary of their grant date and have a term of 10 years, provided, however, as a result of the approval by Company's shareholders of a

500,000 share increase to the 2013 Plan's share reserve in June 2014, the incentive awards were automatically modified to vest monthly over four years effective from their grant date.

The incentive award is a stock based compensation arrangement. From the grant date of each award through June 3, 2014, the Company did not have sufficient shares available for issuance to settle the incentive awards in stock. Since during this period settlement in cash was deemed more likely, the Company accounted for these cash settled awards as a liability to be remeasured at fair value at each reporting date until settled. Through June 3, 2014, compensation expense and the related incentive award liability were recognized over the initial two year vesting period of the incentive awards. On June 3, 2014, once sufficient shares became available to settle the incentive awards in stock, this settlement method was deemed more likely and accordingly, the Company began to account for the incentives awards using the equity accounting method. Specifically, on June 3, 2014, the Company revalued the incentive award liability at fair value, adjusted the expense recognition period to reflect the modified vesting term, and reclassified the resulting $121,000 incentive award liability balance to additional paid in capital. Subsequent to June 3, 2014, the Company recognized the fixed equity value of each incentive award over the remainder of its four year vest period.

As of December 31, 2013, the Company revalued its incentive awards using the Black-Scholes option pricing model and applicable valuation inputs on that date and amortized the resulting value over the initial two year vesting period resulting in $9,000 of stock based compensation expense in the year ended December 31, 2013. A corresponding incentive award liability was recorded in other liabilities in the accompanying balance sheet as of December 31, 2013. During 2014, the Company changed its incentive award accounting from the liability to the equity method and made certain adjustments as noted above. As a result, the Company recorded $285,000 of stock based compensation expense in the year ended December 31, 2014 pertaining to its incentive awards. A corresponding equity adjustment was recorded in additional paid in capital in the accompanying balance sheet as of December 31, 2014.

Stock-Based Compensation Expense

Employee and Director Expense

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

	Year Ended December 31,	
	2014	2013
Research and development	$ 332	$184
General and administrative	952	691
Total	$1,284	$875

Non-Employee Expense

The Company has issued options to purchase shares of common stock to certain scientific advisors and consultants. The stock options have various exercise prices, a term of ten years, and vest over periods up to sixty months. The Company granted to these advisors and consultants options to purchase 10,000 and 6,833 shares of common stock, in 2014 and 2013, respectively. As of December 31, 2014, options to purchase 13,416 shares of common stock remained unvested, and compensation related to these stock options is subject to periodic adjustment as the shares vest. In 2013, the Company also issued an incentive award for 2,335 shares to a scientific advisor, of which 1,752 shares remained unvested as of December 31, 2014. The Company recorded $8,000 and $17,000 of expense in the years ended December 31, 2014 and 2013, respectively, related to these options and awards.

11. 401(k) Plan

The Company provides a qualified 401(k) savings plan for its employees. All employees are eligible to participate, provided they meet the requirements of the plan. While the Company may elect to match employee contributions, no such matching contributions have been made through December 31, 2014 and 2013.

12. Income Taxes

No provision for U.S. income taxes exists due to tax losses incurred in all periods presented. Deferred income taxes reflect the tax effects of net operating loss and tax credit carryforwards and the net temporary differences between the carrying amounts of assets and liabilities for financial reporting and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows (in thousands):

	December 31	
	2014	2013
Deferred tax assets:		
Federal and state net operating loss carryforwards	$ 71,153	$ 60,569
Capitalized research and development	22,314	22,349
Federal and state tax credit carryforwards	7,083	6,600
Other	1,470	1,313
Total deferred tax assets	102,020	90,831
Valuation allowance	(102,020)	(90,831)
Net deferred tax assets	$ —	$ —

Realization of the net deferred tax assets is dependent upon future taxable income, if any, the amount and timing of which is uncertain. Based on the weight of available positive and negative objective evidence, management believes it more likely than not that the Company's deferred tax assets are not realizable. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The net valuation allowance increased by $11.2 million during the year ended December 31, 2014 and decreased $1.8 million during the year ended December 31, 2013.

The following is a reconciliation of the expected statutory federal income tax provision to the actual income tax provision (in thousands):

	December 31	
	2014	2013
Expected income tax benefit at federal statutory tax rate	$(10,851)	$(3,424)
Net operating loss adjustments	(1,703)	4,441
Change in valuation allowance	11,189	(1,757)
State income taxes, net of federal benefit	(783)	583
Permanent items	2,595	555
Research credits	(446)	(396)
Other, net	(1)	(2)
Income tax (benefit) expense	$ —	$ —

Pursuant to Internal Revenue Code ("IRC"), Section 382 and 383, use of the Company's U.S. federal and state net operating loss and research and development income tax credit carryforwards may be limited in the event of a cumulative change in ownership of more than 50.0% within a three-year period. The Company completed an analysis under IRC Sections 382 and 383 through December 21, 2007 and determined that the Company's net operating losses and research and development credits were subject to limitations due to changes in ownership through December 31, 2007. The net operating loss carryforwards reflected in the deferred tax

assets at December 31, 2014 have been adjusted to reflect Section 382 limitations resulting from the ownership change. As the Company was in a net operating loss position for the years 2008-2014, the Company has not performed any additional analysis for IRC Sections 382 and 383 and there is a risk that additional changes in ownership could have occurred since December 31, 2007. If a change in ownership were to have occurred, additional net operating loss and tax credit carryforwards could be eliminated or restricted. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance.

As of December 31, 2014, we had federal net operating loss carryforwards of $181.0 million and state net operating loss carryforwards of $164.6 million to offset future taxable income, if any. In addition, we had federal research and development tax credit carry forwards of $6.7 million and state research and development tax credit carryforwards of $3.2 million. If not utilized, the federal net operating loss and tax credit carryforwards will expire beginning in 2024 through 2034 and the state net operating loss carryforwards will expire beginning in 2015 through 2034. The state tax credit will carry forward indefinitely.

The following table summarizes activity related to the Company's gross unrecognized tax benefits (in thousands):

	Total
Balance as of December 31, 2012	$1,747
Increases related to prior year tax positions	65
Increases related to 2013 tax positions	53
Balances as of December 31, 2013	$1,865
Increases related to prior year tax positions	—
Increases related to 2014 tax positions	126
Balances as of December 31, 2014	$1,991

The unrecognized tax benefits, if recognized, would not have an impact on the Company's effective tax rate. The Company does not expect a significant change to its unrecognized tax benefits over the next twelve months. The unrecognized tax benefits may increase or change during the next year for items that arise in the ordinary course of business.

The Company files income tax returns in the U.S. federal and California jurisdiction and is not currently under examination by federal, state, or local taxing authorities for any open tax years. The tax years 1998 through 2014 remain open to examination by the major taxing authorities.

13. Related-Party Transactions

The Company paid a former member of its Board of Directors, who is also a member of its Scientific and Clinical Advisory Boards, a total of $60,000 and $45,000 in the years ended December 31, 2014 and 2013, respectively, in monthly cash retainers.

14. Subsequent Events

In January and February 2015, the Company utilized its $25 million at-the-market facility to complete sales of its common stock for net proceeds of approximately $4.3 million.

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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.
Registrant

March 23, 2015
Date

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Harold Van Wart and Sujal Shah, as his true and lawful attorney-in-fact and agent, with full power of substitution for him, and in his name in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, and any of them or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1934, this report has been signed by the following persons on behalf of the Registrant in the capacities indicated on the date set forth below:

Name and Signature	Title	Date
/s/ Harold Van Wart Harold Van Wart	Chief Executive Officer and Director *(Principal Executive Officer)*	March 23, 2015
/s/ Sujal Shah Sujal Shah	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 23, 2015
/s/ Louis G. Lange Louis G. Lange, M.D., Ph.D.	Director	March 23, 2015
/s/ Carl Goldfischer Carl Goldfischer, M.D.	Director	March 23, 2015
/s/ Hari Kumar Hari Kumar, Ph.D.	Director	March 23, 2015
/s/ Edward E. Penhoet Edward E. Penhoet, Ph.D.	Director	March 23, 2015
/s/ Kurt von Emster Kurt von Emster, CFA	Director	March 23, 2015
Robert J. Wills, Ph.D.	Director	March 23, 2015

EXHIBIT INDEX

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.)
3.2	Amended and Restated By-Laws. (Filed with the SEC as Exhibit 3.2 to our Amendment No. 2 to Registration Statement on Form 10, filed with the SEC on October 17, 2013, SEC File No. 000-55021.)
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Form of Registration Rights Agreement. (Filed with the SEC as Exhibit 4.2 to our Amendment No. 2 to Registration Statement on Form 10, filed with the SEC on October 17, 2013, SEC File No. 000-55021.)
4.3	Form of 2013 Financing Warrant. (Filed with the SEC as Exhibit 4.3 to our Amendment No. 2 to Registration Statement on Form 10, filed with the SEC on October 17, 2013, SEC File No. 000-55021.)
4.4	Amendment No. 1 to Registration Rights Agreement. (Filed with the SEC as Exhibit 4.4 to our Form 10-K, filed with the SEC on March 31, 2014, SEC File No. 000-55021.)
10.1*	2003 Equity Incentive Plan. (Filed with the SEC as Exhibit 10.1 to our Registration Statement on Form 10, filed with the SEC on August 12, 2013, SEC File No. 000-55021.)
10.2*	Form of 2003 Equity Incentive Plan Stock Option Agreement. (Filed with the SEC as Exhibit 10.2 to our Registration Statement on Form 10, filed with the SEC on August 12, 2013, SEC File No. 000-55021.)
10.3*	Form of 2003 Equity Incentive Plan Early Exercise Stock Option Agreement. (Filed with the SEC as Exhibit 10.2 to our Registration Statement on Form 10, filed with the SEC on August 12, 2013, SEC File No. 000-55021.)
10.4	Form of CymaBay Indemnity Agreement. (Filed with the SEC as Exhibit 10.4 to our Amendment No. 2 to Registration Statement on Form 10, filed with the SEC on October 17, 2013, SEC File No. 000-55021.)
10.5	Loan and Security Agreement, dated September 30, 2013, by and among CymaBay Therapeutics, Inc., Silicon Valley Bank and Oxford Finance LLC. (Filed with the SEC as Exhibit 10.5 to our Amendment No. 2 to Registration Statement on Form 10, filed with the SEC on October 17, 2013, SEC File No. 000-55021.)
10.6#	Development and Clinical Manufacture Agreement, dated June 5, 2012, between Metabolex, Inc. and Patheon Inc. (Filed with the SEC as Exhibit 10.14 to our Amendment No. 3 to Registration Statement on Form 10, filed with the SEC on November 8, 2013, SEC File No. 000-55021.)
10.7#	Standard Development Agreement, dated October 31, 2006, between Metabolex, Inc. and Metrics, Inc. (Filed with the SEC as Exhibit 10.15 to our Amendment No. 3 to Registration Statement on Form 10, filed with the SEC on November 8, 2013, SEC File No. 000-55021.)
10.8#	License and Development Agreement, dated June 30, 1998, between Metabolex, Inc. and DiaTex, Inc. (Filed with the SEC as Exhibit 10.16 to our Amendment No. 3 to Registration Statement on Form 10, filed with the SEC on November 8, 2013, SEC File No. 000-55021.)
10.9#	First Amendment to License and Development Agreement, dated April 15, 1999, between Metabolex, Inc. and DiaTex, Inc. (Filed with the SEC as Exhibit 10.17 to our Amendment No. 3 to Registration Statement on Form 10, filed with the SEC on November 8, 2013, SEC File No. 000-55021.)

Exhibit No.	Description of Document
10.10#	Development and Clinical Manufacture Agreement, dated April 30, 2012, between Metabolex, Inc. and Siegfried AG. (Filed with the SEC as Exhibit 10.18 to our Amendment No. 3 to Registration Statement on Form 10, filed with the SEC on November 8, 2013, SEC File No. 000-55021.)
10.11*	2013 Equity Incentive Plan. (Filed with the SEC as Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on June 6, 2014, SEC File No. 000-55021.)
10.12*	Form of Option Grant Notice and Option Agreement under the 2013 Equity Incentive Plan. (Filed with the SEC as Exhibit 10.26 to our Amendment No. 2 to Registration Statement on Form 10, filed with the SEC on October 17, 2013, SEC File No. 000-55021.)
10.13*	Form of Incentive Award Grant Notice under the 2013 Equity Incentive Plan (Filed with the SEC as Exhibit 10.22 to our Form 10-K, filed with the SEC on March 31, 2014, SEC File No. 000-55021.)
10.14	Lease, dated November 8, 2013, between CymaBay Therapeutics, Inc. and BMR-Pacific Research Center, L.P. (Filed with the SEC as Exhibit 10.27 to our Form 10-Q, filed with the SEC on November 25, 2013, SEC File No. 000-55021.)
10.15*	Offer Letter, dated December 6, 2013, between CymaBay Therapeutics, Inc. and Sujal Shah. (Filed with the SEC as Exhibit 10.24 to our Form 10-K, filed with the SEC on March 31, 2014, SEC File No. 000-55021.)
10.16*	Amendment to Offer Letter, dated November 21, 2013, between CymaBay Therapeutics, Inc. and Harold Van Wart. (Filed with the SEC as Exhibit 10.25 to our Form 10-K, filed with the SEC on March 31, 2014, SEC File No. 000-55021.)
10.17*	Amendment to Offer Letter, dated November 21, 2013, between CymaBay Therapeutics, Inc. and Charles A. McWherter. (Filed with the SEC as Exhibit 10.26 to our Form 10-K, filed with the SEC on March 31, 2014, SEC File No. 000-55021.)
10.18*	Offer Letter, dated February 28, 2014, between CymaBay Therapeutics, Inc. and Pol Boudes. (Filed with the SEC as Exhibit 10.27 to our Form S-1, filed with the SEC on April 8, 2014, SEC File No. 333-195127.)
10.19#	Master Services Agreement, dated February 17, 2014, between CymaBay Therapeutics, Inc. and INC Research, LLC. (Filed with the SEC as Exhibit 10.28 to our Form S-1, filed with the SEC on April 8, 2014, SEC File No. 333-195127.)
10.20*	Non-Employee Director Compensation Policy.
10.21#	PPARδ License Agreement, dated June 20, 2006, by and between Metabolex, Inc. and Janssen Pharmaceutica NV (Filed with the SEC as Exhibit 10.1 to our Form 10-Q, filed with the SEC on November 14, 2014, SEC File No. 001-36500.)
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (incorporated by reference to the signature page of this Annual Report on Form 10-K).
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a)
31.2	Certification of Chief Financial Officer pursuant to Rule 13(a)-14(a)/15d-14(a)
32.1	Certification of Chief Executive Officer and Chief 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	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document

Exhibit No.	Description of Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Document

* Indicates management contract or compensatory plan.

\# Portions of this exhibit have been omitted pursuant to a request for confidential treatment, which portions were omitted and filed separately with the Securities and Exchange Commission.

Exhibit 10.20

CymaBay Therapeutics, Inc.

Amended and Restated
Non-Employee Directors Compensation Program

In January, 2015 our Board adopted an Amended and Restated Non-Employee Director Compensation Program intended to compensate our non-employee directors with a combination of cash and equity. Each non-employee director will receive an annual base cash retainer of $35,000 for such service. The chairman of our board of directors will receive an additional annual base cash retainer of $20,000 for this service. In addition, we intend to compensate the members of our board of directors for service on our committees as follows:

- The chairperson of our audit committee will receive an annual cash retainer of $17,500 for this service, and each of the other members of the audit committee will receive an annual cash retainer of $9,000.
- The chairperson of our compensation committee will receive an annual cash retainer of $10,000 for such service, and each of the other members of the compensation committee will receive an annual cash retainer of $6,000.
- The chairperson of our nominating and corporate governance committee will receive an annual cash retainer of $8,750 for this service, and each of the other members of the nominating and corporate governance committee will receive an annual cash retainer of $4,000.

Cash payments described above shall be paid either quarterly or semi-annually at the discretion of the board member. Further, at about the time of our annual meeting of stockholders, each non-employee director will receive an additional equity award of an option to purchase 9,000 shares of our common stock. If a new board member joins our board of directors, the director will receive an initial stock option to purchase 18,000 shares of our common stock. Annual option grants and option grants to new board members will be subject to vesting as determined by our Board or Compensation Committee on the date of grant.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statements (Form S-3 File Nos. 333-200006 and 333-192617) of CymaBay Therapeutics, Inc., and

(2) Registration Statements (Form S-8 File Nos. 333-195211 and 333-198289) pertaining to the Metabolex, Inc. 2003 Equity Incentive Plan, and the CymaBay Therapeutics, Inc. 2013 Equity Incentive Plan, of our reports dated March 23, 2015, with respect to the financial statements of CymaBay Therapeutics, Inc. included in this Annual Report (Form 10-K) of CymaBay Therapeutics, Inc. for the year ended December 31, 2014.

/S/ ERNST & YOUNG LLP

Redwood City, California
March 23, 2015

Exhibit 31.1

CERTIFICATION

I, Harold Van Wart, certify that;

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

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

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

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

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

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

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

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

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

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

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

Date: March 23, 2015

/s/ Harold Van Wart

Harold Van Wart
Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Sujal Shah, certify that;

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

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

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

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

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

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

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

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

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

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

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

Date: March 23, 2015

/s/ Sujal Shah

Sujal Shah
Chief Financial Officer and Secretary
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION

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

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2014, to which this Certification is attached as Exhibit 32.1 (the "Annual 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 Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned have set their hands hereto as of the 23rd day of March, 2015.

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

This certification accompanies the Form 10-K 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-K), irrespective of any general incorporation language contained in such filing.