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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, 2016**

**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, 2016, was $37,357,482. This excludes 1,977,186 shares of the registrant's Common Stock held by executive officers, directors and stockholders affiliated with directors outstanding at June 30, 2016. 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, 2017, was 28,752,451.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's Proxy Statement for its 2017 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, 2016, are incorporated by reference in Part III, Items 10-14 of this Annual Report on Form 10-K.

**CYMABAY THERAPEUTICS, INC.**
**ANNUAL REPORT ON FORM 10-K**
**For the Year Ended December 31, 2016**

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## CAUTIONARY LANGUAGE REGARDING FORWARD-LOOKING STATEMENTS

*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," "projected," "potential," "seek," "target," "goal," "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 specialty and orphan diseases with high unmet medical need. Our two key clinical development candidates are seladelpar and arhalofenate.

We are currently developing seladelpar (MBX-8025) for the treatment of primary biliary cholangitis (PBC), an autoimmune disease that causes progressive destruction of the bile ducts in the liver. Seladelpar is a potent and selective agonist of PPARd, a nuclear receptor that regulates genes important for lipid, bile acid/sterol and glucose metabolism and for inflammation in liver and muscle. In May 2016, we announced results from a Phase 2 clinical study of seladelpar in patients with PBC. The study was intended to enroll approximately 75 patients with PBC who had an inadequate response to ursodiol and randomize them to receive either placebo or seladelpar (either 50 mg or 200 mg) once-daily for 12 weeks. Despite the occurrence of three cases of asymptomatic, reversible transaminase elevations (two in the 200 mg and one in the 50 mg groups), data from 35 patients evaluated for efficacy demonstrated that treatment with seladelpar resulted in statistically significant reductions in the primary endpoint of serum alkaline phosphatase (ALP). The mean decreases from baseline in ALP for the 50 and 200 mg dose groups were 53% and 63%, respectively, vs. 2% for placebo ($p < 0.0001$ for both). Based on results from a number of published studies, lower levels of ALP have been shown to correlate with a significant reduction in adverse clinical outcomes for PBC patients including liver transplant and/or death. All patients who received seladelpar treatment for 12 weeks (three on 50 mg and two on 200 mg) had their ALP values restored to within the normal range. The study was discontinued early after review of safety and efficacy data demonstrated proof-of-concept for activity on cholestatic biomarkers and had identified the need to reduce the dose in order to optimize for clinical safety and efficacy. In October 2016, seladelpar received European Medicines Agency (EMA) PRIority MEdicines (PRIME) designation for the treatment of PBC. The U.S. Food and Drug Administration (FDA) granted orphan drug designation to seladelpar for the treatment of PBC in November 2016. In December 2016, we initiated a dose-ranging Phase 2 study of seladelpar at lower daily doses of 5 and 10 mg in patients with PBC.

In March 2016, we announced results from a Phase 2 clinical study evaluating seladelpar in 13 patients with homozygous familial hypercholesterolemia (HoFH), a rare, life-threatening, genetic disease characterized by marked elevations in plasma levels of low density lipoprotein (LDL-C) leading to severe atherosclerosis and the development of premature cardiovascular diseases. Five patients in this study experienced what we believe was a clinically meaningful maximal decrease in LDL-C of greater than 20% with three of them having decreases greater than 30%. Levels of human proprotein convertase subtilisin kexin 9 (PCSK9) increased during seladelpar treatment by an average of 43%. PCSK9 is a protein that targets degradation of low density lipoprotein receptor (LDL-R) on the surface of liver cells. Cell surface LDL-R regulates circulating levels of LDL-C and decreases in LDL-R are known to result in corresponding increases in LDL-C. This means that while seladelpar lowered LDL-C, it did so in the face of simultaneous increases in PSK9 elevations, the latter effect likely opposed the tendency of seladelpar to decrease LDL-C. This suggests that seladelpar should be tested for LDL-C lowering in HoFH patients as an add-on therapy to maximal conventional lipid lowering therapy and PCSK9 inhibitor therapy, since PCSK9 inhibitors could remove the confounding effect of PCSK9 elevation caused by seladelpar and hence lead to even greater reductions in LDL-C.

We also believe that seladelpar could have utility in the treatment of severe hypertriglyceridemia (SHTG) and the more prevalent, but high unmet need, indication of nonalcoholic steatohepatitis (NASH). We have obtained orphan-drug designations for seladelpar in PBC, HoFH and SHTG (Frederickson type I or V hyperlipoproteinemia).

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

In late December 2016, we entered into an exclusive licensing agreement with Kowa Pharmaceuticals America, Inc. (Kowa) for the development and commercialization of arhalofenate in the U.S. (including all its possessions and territories). Under the terms of the agreement, we received an up-front payment of $5 million in January 2017, and will receive potential milestone payments of up to $10 million based on the initiation of specific development activities, and are eligible to receive up to an additional $190 million in payments based upon the achievement of specific development and sales milestones. We are also eligible to receive tiered, double digit royalties on future sales of arhalofenate products. Kowa will be responsible for all development and commercialization costs. We retain full development and commercialization rights for the rest of the world and intend to partner arhalofenate in geographies outside the U.S. and its possessions and territories.

We reported net loss of approximately $26.7 million and $15.5 million for the years ended December 31, 2016, and 2015, respectively. Our average monthly cash usage for the year ended December 31, 2016, was approximately $2.1 million. As of December 31, 2016, we had cash, cash equivalents and marketable securities of approximately $17.0 million. We believe that these funds, which were obtained through recent equity and debt financings, together with additional proceeds of approximately $14.4 million received from financings and license agreements in January and February of 2017, will allow us to continue operation through at least the next twelve months.

**CymaBay Strategy**

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

- develop seladelpar for patients with PBC;

- develop seladelpar for other high unmet need or orphan indications focused on liver and lipid diseases;
- partner with third-parties for the development and commercialization of arhalofenate outside the U.S. for patients with gout; and
- advance the development of other product candidates in our pipeline through our own efforts or through collaborations with third-parties.

**CymaBay Pipeline Overview**

Our pipeline includes three clinical stage product candidates and one preclinical program.

**Seladelpar (MBX-8025)**

Seladelpar is a selective agonist for the peroxisome proliferator-activated receptor delta (PPARd). An agonist is a substance that elicits a response by binding to a receptor. The PPARd receptor is a nuclear receptor that regulates genes involved in lipid, bile acid/sterol and glucose metabolism (particularly de novo lipogenesis and fatty acid oxidation), in insulin signaling and sensitivity, and in regulation of certain inflammatory cells. Seladelpar has the potential to treat a variety of disorders of lipid metabolism and certain diseases of the liver. Previously, seladelpar 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 seladelpar 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, seladelpar demonstrated an anti-atherogenic profile in which it lowered LDL-C, decreased the more atherogenic small dense LDL-C particles and raised high-density lipoprotein (HDL-C). In addition, seladelpar decreased TGs and free fatty acids. Seladelpar also decreased C-reactive protein, a marker of systemic and local inflammation. Treatment with seladelpar also resulted in significant reductions in alkaline phosphatase (ALP) and in gamma-glutamyl transferase (GGT). Taken together these metabolic improvements suggest that seladelpar can address disorders manifested by increases in LDL-C, increases in TGs, liver cholestasis (the impairment of the flow of bile from the liver) and liver fat accumulation with subsequent inflammation.

Based on an evaluation of possible indications, we have decided to focus the development of seladelpar 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 seladelpar 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 partial clinical hold is based on 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 seladelpar and have had discussions with the FDA regarding them. We have also completed additional experiments seeking to confirm that the findings are not relevant to human risk. Our goal is to provide those data together with clinical data from our completed and ongoing phase 2 studies in PBC to the FDA so that they can determine whether to lift the partial clinical hold. The decision on timing to meet with the FDA to discuss lifting the partial clinical hold is contingent on the availability and strength of the results from our PBC studies. We will make those decisions when the results have been obtained and interpreted.

We believe seladelpar 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 cholangitis (PBC). We also believe that seladelpar could have utility in the treatment of the more prevalent, but high unmet need indication of nonalcoholic steatohepatitis (NASH).

***Nonclinical Overview***

*In vitro* studies with cells and animal tissues, showed that seladelpar up-regulates genes involved in the metabolism and handling of lipids, most notably stimulation of fatty acid synthesis, transport and oxidation.

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

Six month and twelve month toxicology studies in rats and monkeys, respectively have been completed. 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 Seladelpar***

Five Phase 1 and three Phase 2 clinical studies with seladelpar have been completed. A fourth Phase 2 clinical study is currently ongoing in patients with PBC. The first phase 2 clinical trial in overweight and obese patients with mixed dyslipidemia was an eight-week trial in which seladelpar was administered at doses of 50 or 100 mg/day both alone and in combination with 20 mg/day of atorvastatin. This study also had a placebo arm and a 20 mg/day atorvastatin monotherapy arm. Treatment effects with seladelpar observed in this study included lowering of LDL-C with selective depletion of pro-atherogenic dense LDL-C particles, decreases in triglycerides and increases in HDL. Patients taking seladelpar also experienced decreased levels of alkaline phosphatase and gamma glutamyl transferase, which when elevated are biochemical markers of cholestasis.

Based on our understanding of the mechanism of action of seladelpar and our prior clinical experience with the compound, we have redirected the development of seladelpar toward serious rare and orphan diseases or more prevalent diseases with higher unmet medical need.

**Primary Biliary Cholangitis (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 U.S. and in the E.U. It is a long-term debilitating and life-threatening disease. Fatigue and pruritus (itching) are the most common presenting symptoms. Pruritus, 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 treatments are ursodeoxycholic acid (UCDA), also known as ursodiol, an isomer of chenodeoxycholic acid and the synthetic bile acid analog obeticholic acid (Ocaliva®, Intercept Pharmaceuticals). Ursodiol decreases serum levels of ALP, 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 adequately to ursodiol therapy.

Ocaliva was approved by the FDA and European Medicines Agency in 2016 for the treatment of PBC in combination with ursodiol in adults with an inadequate response to ursodiol, or as monotherapy in adults unable to tolerate ursodiol. Ocaliva also received orphan designations in the U.S. and the E.U. A Phase 3 study was completed with a primary composite endpoint defined as a responder rate comprised of the percentage of patients with ALP < 1.67 times upper limit of normal (ULN) with a decrease in ALP of at least 15% and total bilirubin less than or equal to upper limit of normal. This study met its goals and Ocaliva was granted an accelerated approval based on meeting this primary composite endpoint.

Additional potential therapies in clinical development for PBC include LJN452 and GS9674, both of which are non-bile acid analogs and the mixed PPARa/d agonist elafibranor. Other therapies, such as colchicine, methothrexate, prednisone and multiple immunosuppressive regimens have been attempted. However, these unproved therapies have efficacy that 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 transplant 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.

***Phase 2 Studies of Seladelpar in PBC***

In November 2015, we initiated a Phase 2 study of seladelpar in patients with primary biliary cholangitis. The study was a placebo controlled, double blind, dose ranging study of 12 weeks duration in patients who had an inadequate response to ursodiol, as characterized by a persistent elevation in ALP. The study planned to enroll approximately 75 patients who were randomized to receive placebo, 50 or 200 mg daily doses of seladelpar. The goal of the study was to assess whether the improvements in biochemical markers of cholestasis observed previously for seladelpar in other patient populations would be observed in patients with PBC.

The primary endpoint was the percent change in ALP. A secondary endpoint was the responder rate for patients achieving the composite criteria of serum ALP values less than 1.67xULN with a decrease of at least 15% and with normal levels of total bilirubin (TBIL). ALP values were blinded, but other secondary endpoints that are also recognized as biochemical markers of cholestasis, such as changes in GGT, TBIL and 5'-nucleotidase, were only blinded with respect to treatment group because they were part of the safety surveillance.

During the study, three cases of asymptomatic increases in transaminases were observed (two in the 200 mg and one in the 50 mg cohorts). All three were reversible on discontinuation of treatment and were not accompanied by elevation of TBIL. After unblinding of study data, changes in the primary endpoint ALP were analyzed using data available for the 38 subjects enrolled in the study and who had completed at least two weeks of treatment. The primary analysis of changes in ALP were calculated using the last observation carried forward (LOCF) as specified in the study statistical analysis plan.

The mean decreases from baseline in ALP for the 50 and 200 mg dose groups were 53% and 63%, respectively, vs. 2% for placebo ($p < 0.0001$ for both). There was no statistically meaningful difference in efficacy between both seladelpar groups. All patients on seladelpar who received treatment for 12 weeks (three on 50 mg and two on 200 mg) experienced normalization of their ALP. Thus, in this study seladelpar demonstrated a rapid and potent anti-cholestatic effect in patients with PBC. The lack of a dose response suggests that lower doses could be effective as well.

**Summary of Treatment Effects on Alkaline Phosphatase**

| Treatment Group | N | Baseline (U/L) | Change (%) |
|---|---|---|---|
| **Placebo** | **12** | **233** | **-2** |
| **Seladelpar (50 mg)** | **13** | **312** | **-53*** |
| **Seladelpar (200 mg)** | **10** | **248** | **-63*** |

***p < .0001 vs. placebo**

Patients receiving study drug also demonstrated improvements in metabolic parameters, including reductions from pre-treatment levels of LDL-C of 13% and 16% for the 50 and 200 mg dose groups, respectively, vs. 3.7% for placebo after two weeks of dosing. Seladelpar was also associated with a decrease in a plasma marker of hepatic bile acid synthesis, 7a-hydroxy-4-cholesten-3-one (C4). Seladelpar did not appear to be associated with drug-induced pruritus. In summary, the study was discontinued early after review of safety and efficacy data demonstrated proof-of-concept for anti-cholestatic effects and it was recognized that another study was needed with further dose reduction in order to establish optimal clinical safety and efficacy.

In December 2016, we initiated a second Phase 2 study of seladelpar in patients with PBC. In this open label study, patients who have had an inadequate response to, or who are intolerant to, ursodiol will be enrolled to receive seladelpar, either 5 or 10 mg, for 8 weeks. Based on the review of the 8-week data, new patients will be enrolled to receive seladelpar 25 mg for 8 weeks. The study also incorporates an extension phase where patients will be able to continue treatment for a total of 26 weeks during which it will be possible to adjust the dose of seladelpar. The primary endpoint will be the change in ALP. A variety of secondary outcomes will also be studied. We are planning to enroll approximately 36 patients in the U.S., Canada, Germany, and the U.K.

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

NAFLD is a disease characterized by accumulation of fat in the liver in individuals that consume little or low amounts of alcohol (< 70 g/week for women and < 140 g/week for men). 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 testing. 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, several clinical studies have been carried out or are underway with drug candidates that may affect disease outcomes in patients with NASH, including Phase 3 studies with OCA (Intercept Pharmaceuticals) and elafibranor (GFT505), a PPARa/d agonist (Genfit SA).

Based on data from our Phase 2 clinical trial in patients with mixed dyslipidemia and available data from other PPARd agonists, we believe seladelpar 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 PPARd agonist GW501516. A short term clinical trial with GW501516 demonstrated that the compound decreased hepatic fat. In addition to our clinical experience with seladelpar, along with that of other PPARd agonists, the well documented property that seladelpar 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. Recently, seladelpar was found to decrease fibrosis, inflammation, hepatic lipids and reverse insulin resistance on the *foz/foz* mouse which is a diabetic obese mouse model of NASH. We continue to evaluate the opportunity to develop seladelpar in NASH among a number of additional indications.

**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 copies of the low-density lipoprotein receptor (*ldlr*) gene, leading to reduced or absent LDL-receptor protein (LDL-R) function. The disease affects approximately one in one million persons. The loss of LDL-R function leads to impaired removal of circulating LDL-C by the liver, 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. HoFH subjects sometimes undergo a procedure called LDL-C apheresis, a process resembling dialysis in which blood is removed from a patient, the plasma is separated from blood cells, and the plasma is passed over a column to remove LDL prior to recombining it with the blood cells and returned to the patient. The reduction in LDL-C by apheresis has been shown to reduce cardiovascular events in HoFH patients. Initial treatment of HoFH entails adoption of a low fat diet and exercise program, usually with limited effectiveness. This is followed by first-line 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 do not provide optimal control of LDL-C 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.

As mentioned above, LDL apheresis is complicated mechanical method to reduce LDL-C and is currently a treatment of last resort for HoFH. It is a complex and inconvenient procedure that sometimes requires an arterio-venous fistula, similar to the situation for patients undergoing chronic dialysis. The procedure is not widely available. Apheresis transiently reduces LDL-C, but rebound of LDL-C levels requires that it be repeated chronically every one to two weeks.

Several drugs have been recently 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.

The third and most recently approved drug for HoFH is evolocumab (Repatha, Amgen Inc.). Evolocumab is a human monoclonal IgG2 antibody directed against human proprotein convertase subtilisin kexin 9 (PCSK9). Evolocumab binds to PCSK9 and inhibits circulating PCSK9 from binding to the LDL-R, preventing PCSK9 targeting of LDL-R degradation and permitting LDL-R to recycle back to the liver cell surface. By inhibiting the binding of PCSK9 to LDL-R, evolocumab increases the number of hepatic cell surface LDL-Rs available to clear LDL from the blood, thereby lowering LDL-C levels.

While these 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.

In January 2015, we announced preclinical data demonstrating the potential of seladelpar to treat patients with HoFH. Seladelpar gave durable and significant decreases in LDL-C concentrations of greater than 40% in the Watanabe Heritable Hyperlipidemic rabbit, an accepted preclinical model of human HoFH. Based on this preclinical data, our understanding of the mechanism of action of seladelpar and the remaining unmet need for these patients despite the approval of recent therapies, we conducted a Phase 2 pilot study of seladelpar in HoFH patients.

***Phase 2 Study of Seladelpar in HoFH***

In April 2015, we initiated a Phase 2 study of seladelpar in patients with HoFH. This was an open label, dose escalation study of 12 weeks duration conducted at five centers in Europe and Canada. Thirteen patients were enrolled, all of whom had genetically confirmed HoFH, including 2 subjects who had functionally negative mutations in their LDL-R genes. All of the subjects were taking ezetimibe and were on maximum statin therapy. None of the study participants received lomitapide, mipomersen or a PCSK9 inhibitor. Eight patients were undergoing concomitant apheresis on a weekly or biweekly schedule. Despite being on maximal conventional therapy, the average baseline LDL-C was 368 mg/dL. Subjects received once daily treatment with 50 mg of seladelpar for 4 weeks, after which the dose was escalated to 100 and 200 mg in successive 4 week periods. The goals of the study were to evaluate the effect on LDL-C as well as a spectrum of other lipid-related parameters, including PCSK9 levels, and to collect safety information.

Two different per-protocol analyses were performed on 12 subjects. A responder analysis was carried out which reflects the largest decrease in LDL-C observed during treatment for each subject. Three subjects (25%) exhibited a greater than or equal to 30% decrease. Five subjects (42%) had a greater than or equal to 20% decrease, including one patient that was receptor negative and seven subjects (58%) had a greater than or equal to 15% decrease. Five subjects had a less than 15% decrease. The average maximum decrease in the study was 19%. Because of the high baseline LDL-C levels in these individuals, these percentage decreases correspond to significant absolute decreases in LDL-C (mean decrease of 109 mg/dL for the subjects with the greater than or equal to 15% decrease). Although reductions in LDL-C tended to be greater at the higher doses, no clear dose response was observed.

In a second analysis, the mean change in LDL-C for each subject was calculated by averaging values across all doses and dosing periods while on treatment. The overall mean change for all 12 subjects was a decrease of 10%. Eight of these subjects had a mean decrease in LDL-C of 16%, including three with a greater than 20% decrease. This included one patient who was receptor negative. This was offset by four patients who showed a mean increase of 4%.

Mean PCSK9 was elevated at baseline (544 +/- 133 ng/mL), as anticipated for patients with HoFH, and increased during treatment by a mean of 43%. During the study, decreases in the mean levels of alkaline phosphatase (30%), gamma glutamyl transferase (27%) and total bilirubin (22%), which are markers of cholestasis, were also observed. There were three severe adverse events (SAEs), none drug related, and three treatment discontinuations for adverse events (AEs) possibly related to seladelpar.

The LDL-C levels of most HoFH patients are not optimally controlled and there is still a need for new therapeutic approaches. The finding that seladelpar lowers LDL-C while raising PCSK9 indicates that the full potential of seladelpar should be evaluated when treating HoFH patients on a background of maximal conventional lipid lowering therapy and a PCSK9 inhibitor. We are currently evaluating the feasibility of such a study.

**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 U.S. 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 (lipoprotein particles formed in the intestine that are rich in TGs and which serve to transport lipid to other tissues in the body) are markedly elevated due to decreased activity of liporprotein lipase (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. Elevated chylomicrons are thought to have a number of consequences including increased risk of acute and chronic pancreatitis which are serious medical conditions. Extremely high levels of TGs are a surrogate marker for high chylomicron levels.

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 seladelpar may be 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.

**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.

***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 lower sUA by promoting the excretion of uric acid by the kidney. Lesinurad (Zurampic ®, Ironwood Pharmaceuticals, Inc. and AstraZeneca PLC) is a uricosuric that blocks URAT1, the main urate transporter/exchanger in renal proximal tubules. Zurampic 200mg in combination with a xanthine oxidase inhibitor was approved in the U.S. in 2015 and in the E.U. in 2016 for the treatment of hyperuricemia associated with gout in patients that have not reached target serum uric acid levels with an XO inhibitor alone. The FDA approved Zurampic with a black-box warning regarding the potential for acute renal failure and the approved indication is restricted to its use in combination with an XO inhibitor.

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. Long term use of colchicine 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 Has the Potential to Address 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 an investigational 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 febuxostat to increase the number of patients reaching their desired sUA targets, to limit the number of flares and, in patients with tophaceous gout, to potentially resolve tophi.

**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. Collectively across these studies, we evaluated the safety and efficacy of arhalofenate in doses ranging from 400 mg – 800 mg as monotherapy and in combination with the two approved XO inhibitors, allopurinol and febuxostat. The results of these studies collectively support further development of arhalofenate as a potential urate-lowering anti-flare therapy (ULAFT) for the large number of gout patients that are inadequate responders or are intolerant to XO inhibitors.

***Conclusions of Arhalofenate's Clinical Experience***

Arhalofenate has been studied in a total of 17 clinical studies with over 1,100 subjects in healthy volunteer, type 2 diabetic and gout populations. 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 with a safety profile that supports development for gout.

In clinical studies conducted to date that included over two hundred patients with hyperuricemia and a diagnosis of gout, arhalofenate was found to be well tolerated when dosed at 400 mg, 600 mg or 800 mg once daily up to twelve weeks. Arhalofenate treatment resulted in reductions in sUA whether administered alone or in combination with a XO inhibitor. As a uricosuric, arhalofenate decreases sUA by increasing the urinary excretion of uric acid. In clinical trials to date, Arhalofenate has increased the fractional excretion of uric acid with levels that were at or near normal without overcorrection.

In addition, arhalofenate when administered at 800 mg daily without colchicine decreased the incidence of flares and also increased the proportion of patients not experiencing any flare. Activity against flares would address one of the most burdensome symptoms for gout patients.

***Gout Partnership with Kowa Pharmaceuticals America, Inc.***

In late December 2016, we entered into an exclusive license agreement with Kowa for the development and commercialization of arhalofenate in the U.S. Pursuant to the license agreement, we granted to Kowa an exclusive license to certain patent rights and technology related to arhalofenate. Kowa will have exclusive rights to, among other things, develop, use, manufacture, sell and otherwise exploit the licensed technology in the United States (including all possessions and territories).

We plan to enter into licensing agreements with other parties for development and commercialization rights to arhalofenate in other geographies.

**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**

We actively seek to obtain, where appropriate, patent protection and regulatory exclusivity for the proprietary technology that we consider important to our business, including compounds, compositions and formulations, their methods of use and processes for their manufacture both in the United States and other countries. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing to develop and maintain our 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 us complete protection against competitors who seek to circumvent our patents.

We also depend upon the skills, knowledge, experience and know-how of our management, research and development personnel, as well as that of our advisors, consultants and other contractors. To help protect our proprietary know-how, which is not patentable, and for inventions for which patents may be difficult to enforce,

we currently rely, and will in the future rely, on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all of our 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 us of the ideas, developments, discoveries and inventions important to our business.

**Collaborations and Licensing Agreements**

We have entered into various arrangements with licensors and licensees. The current collaborations are summarized below.

**Kowa Pharmaceuticals America, Inc.:** In December 2016, we entered into an exclusive license agreement with Kowa Pharmaceuticals America, Inc. for the development and commercialization of arhalofenate in the U.S. Pursuant to the license agreement, we granted to Kowa an exclusive license to certain patent rights and technology related to arhalofenate. Kowa will have exclusive rights to, among other things, develop, use, manufacture, sell and otherwise exploit the licensed technology in the United States (including all possessions and territories). Under the license agreement, Kowa paid us an up-front payment of $5 million in January 2017, and has agreed to pay us potential milestone payments of $10 million based on the initiation of specific development activities, potential milestone payments of $190 million upon the achievement of additional development and sales milestones, and tiered, double digit royalties on future net sales of arhalofenate products. Kowa is responsible for all development and commercialization costs in the US. We retain full development and commercialization rights for the rest of the world.

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

In June 2010, we 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. We received a termination notice from Janssen, effectively ending these development and licensing agreements in early April 2015. In December 2015, we exercised an option pursuant to the terms of one of the original agreements to continue work to research, develop and commercialize compounds with activity against an undisclosed metabolic disease target. Janssen granted us an exclusive, worldwide license (with rights to sublicense) under the Janssen know-how and patents to research, develop, make, have made, import, use, offer

for sale and sell such compounds. We have full control and responsibility over the research, development and registration of any products developed and/or discovered from the metabolic disease target and are required to use diligent efforts to conduct all such activities.

**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. On December 23, 2016 the agreement was amended by the parties to change the timing of a specified development milestone and that DiaTex will join as a party plaintiff any enforcement action brought to enforce the licensed patents against third parties. The amendment also provided that if we breach the agreement or if the agreement is terminated for any reason DiaTex will allow our sublicensee to cure such breach or enter into a new license agreement directly with such sublicensee on the terms and conditions of our agreement with 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 of arhalofenate in gout. 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 exceeded approximately $8 million through 2015. 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.

**Pharmaceutical Research Associates, Inc.:** In September 2015, we entered into a Master Services Agreement with Pharmaceutical Research Associates, Inc (PRA) and related initial work order for PRA to provide contract clinical research and development services to us in connection with our Phase 2 study of seladelpar in PBC. Under this agreement, we may engage PRA from time to time in accordance with mutually agreed work orders. The initial work order includes services for our clinical candidate, seladelpar, and the total costs under such initial work order are anticipated to be approximately $6.2 million. The agreement provides for performance of services by PRA in compliance with work orders, industry standards, FDA and ICH requirements and all applicable laws. We remain responsible for all regulatory responsibilities unless specifically transferred to PRA, as well as the determination of any work orders, subject to mutual agreement on the specific terms of any such work orders. The agreement has a term of five years, and we can terminate the agreement or any individual work order upon thirty (30) days written notice. In addition, either party may terminate the agreement or any applicable work order upon thirty (30) days written notice for an uncured material breach by the other party, or immediately in the event of the other party's bankruptcy, insolvency, liquidation or assignment for the benefit of creditors. On July 25, 2016 we entered into a second work order for services for our clinical candidate seladelpar and the total costs under such work order are anticipated to be approximately $6.4 million.

**Intellectual Property**

We own and co-own approximately 41 United States patents, 192 foreign patents, as well as 19 United States patent applications and 164 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 18 United States patents and 2 United States patent applications, 316 foreign patents and 57 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 151 issued patents and 77 pending patent applications relating to composition, method of use or methods of manufacture. We believe our issued patents protect Arhalofenate through at least 2019-2032 before accounting for any potential patent term extension. The seladelpar portfolio consists of approximately 339 issued patents and 126 pending patent applications related to composition and method of use that we believe protect it through at least 2024-2035 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.

**Manufacturing**

We do not currently own or operate manufacturing facilities for the production or testing of seladelpar, arhalofenate or other product candidates that we develop, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We presently depend on third party contract manufacturers to obtain all of our required raw materials, Active Pharmaceutical Ingredients (APIs) and finished products for our clinical studies for seladelpar. We have executed manufacturing agreements for our API and clinical supplies of seladelpar and arhalofenate 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 seladelpar and arhalofenate are available from more than one source.

***Ash Stevens, Inc.***

On May 10, 2016 we entered into a Development and Clinical Supply Agreement with Ash Stevens for the manufacturing of API necessary for the development and manufacture of seladelpar drug product. Under the agreement, Ash Stevens shall obtain the raw materials necessary for the API. We own the rights, title and interest to the deliverables and intellectual property covering the deliverables generated under the agreement. Both Ash Stevens and we 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. We may terminate the agreement at any time with written notice. In addition, either party may terminate the agreement at any time for material breach under the agreement.

***Xcelience, Inc.***

On October 20, 2016 we entered into a Development and Clinical Supply Agreement with Xcelience, Inc. Under the agreement, Xcelience will provide us with pharmaceutical development, formulation and analytical services. The schedule of services, deliverables and pricing terms will be set forth in one or more written work orders to be entered into and mutually agreed upon by the parties from time to time. We will own the rights, title and interest to the intellectual property relating to all pharmaceutical products developed or manufactured for us by Xcelience, as well as any active pharmaceutical ingredient provided to Xcelience by us. We have agreed to indemnify Xcelience against third party claims that involve the breach by us of any of our obligations, warranties or representations under the agreement, and Xcelience has agreed to indemnify us against third party claims that involve (i) the negligence, gross negligence, or intentional misconduct on the part of Xcelience, (ii) a failure by Xcelience to comply with the law in their performance of the agreement, or (iii) a breach of Xcelience's obligations, covenants, representations, or warranties under the agreement. Either party may terminate the agreement at any time with advance written notice.

***Metrics Inc.***

On October 31, 2006, we entered into a Standard Development Agreement with Metrics, Inc. Under the agreement, Metrics will provide us with pharmaceutical development, formulation and analytical services in consideration of which we will provide appropriate compensation as outlined in the agreement. We own the rights, title and interest to the intellectual property relating to all pharmaceutical products developed or manufactured for us by Metrics, as well as any active pharmaceutical ingredient provided to Metrics by us. We have agreed to indemnify Metrics against third party claims that involve the breach by us of any of our obligations, warranties or representations under the agreement, and Metrics has agreed to indemnify us 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.

***Siegfried AG***

On April 30, 2012, we 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, we shall deliver or Siegfried shall obtain the raw materials necessary for the API. We own 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 us to use Siegfried intellectual property to exploit any product or service based or derived from the deliverables under the agreement. Both Siegfried and we 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. We may terminate the agreement at any time with written notice and Siegfried may terminate the agreement in the event we discontinue our 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, we entered into a Development and Clinical Manufacture Agreement with Patheon Inc. for the manufacturing of the tablet form of arhalofenate. Under the agreement, we shall deliver the API or Patheon shall obtain the API from a qualified vendor. We own the rights, title and interest to the deliverables and intellectual property generated by Patheon in connection with the performance of the services for us under the agreement. Both Patheon and we 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. We may terminate the agreement at any time with written notice provided that we terminate 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.

**Competition**

The biopharmaceutical industry is highly competitive and subject to rapid and significant innovation. Although we believe that our development expertise and scientific knowledge provide us with advantages over our competitors, particularly in the therapeutic areas in which we are focused, other biopharmaceutical companies in the industry may be able to develop therapeutics that are able to achieve better results. Our competitors include pharmaceutical companies, biotechnology companies, specialty pharmaceutical companies, universities and other research institutions. Many of our competitors may have significantly greater financial, technical and human resources than we have.

We are currently developing seladelpar for the treatment of patients with primary biliary cholangitis (PBC). Currently, the only FDA-approved treatments for PBC are ursodeoxycholic acid (UCDA), also known as ursodiol, an isomer of chenodeoxycholic acid and the synthetic bile acid analog obeticholic acid (Ocaliva®, Intercept Pharmaceuticals). Ursodiol decreases serum levels of ALP, 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 adequately to ursodiol therapy. Ursodiol is available as a generic and is priced at a discount to typical branded therapies.

Ocaliva was approved by the FDA and European Medicines Agency in 2016 for the treatment of PBC in combination with UDCA in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA. Ocaliva also received orphan designations in the U.S. and the E.U. A Phase 3 study was completed with a primary composite endpoint defined as a responder rate comprised of the percentage of patients

with ALP < 1.67 times upper limit of normal with a decrease in ALP of at least 15% and total bilirubin less than or equal to upper limit of normal. This study met its goals and Ocaliva was granted accelerated approval based on meeting this primary composite endpoint.

Although not approved for use in PBC, off-label use of fibrate drugs has been reported, though many fibrates are specifically contraindicated for use in PBC due to potential concerns over acute and long-term safety in this patient population. 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.

We are aware of a number of companies with development programs in PBC that are currently in or beyond phase 2 including, LJN452 (Novartis Pharmaceuticals Corporation) and GS9674 (Gilead Sciences, Incorporated), both of which are non-bile acid analogs and the mixed PPARa/d agonist elafibranor (Genfit S.A.).

Arhalofenate is being developed for the treatment of patients with gout. The xanthine oxidase inhibitors, allopurinol and febuxostat (marketed by Takeda Pharmaceutical Company Limited as Uloric®), are the most commonly prescribed drugs to lower uric acid in patients with gout. Lesinurad (Zurampic®, Ironwood Pharmaceuticals, Inc. and AstraZeneca PLC) is a uricosuric that blocks URAT1, the main urate transporter/exchanger in renal proximal tubules. Zurampic 200mg in combination with a xanthine oxidase inhibitor is approved in the U.S. and in the E.U. for the treatment of hyperuricemia associated with gout in patients that have not reached target serum uric acid levels with a xanthine oxidase inhibitor alone. Pegloticase (marketed by Horizon Pharma plc as KRYSTEXXA®) is a PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy. Anti-inflammatory drugs, such as colchicines, steroids and NSAIDs, are prescribed to manage gout flares.

**Research & Development Costs**

Our research and development costs for the years ended December 31, 2016 and 2015, all of which are borne by us, were $15.9 million and $17.0 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 we are developing. The pharmaceutical drug product candidates that we develop 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 us. 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. The conduct of the preclinical tests 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 by way of a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin. 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. Submission of an IND may not result in the FDA allowing clinical studies to begin and, once begun, issues may arise that lead to suspension or termination of 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 we interpret the same data. The FDA will issue a complete response letter if

the agency decides not to approve the NDA. The complete response letter describes 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 we receive 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.

Manufacturers of our 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 us, 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 healthcare laws have been applied to restrict certain business practices in the biopharmaceutical industry in recent years. These laws include anti-kickback statutes, false claims statutes, data privacy and security laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers. 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 our 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 intent standard 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 Reconciliation Act, or collectively the PPACA, so that 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).

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. Additionally, the civil monetary penalties statute 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 Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional 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.

The federal Physician Payments Sunshine Act, created under the PPACA, and its implementing regulations, require certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually information related to certain payments or other transfers of value provided to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals, and applicable manufacturers and group purchasing organizations to report annually certain ownership and investment interests held by physicians and their immediate family members.

We may also 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 for Economic 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.

The majority of states also have statutes or regulations similar to the aforementioned federal fraud and abuse laws, some of which are broader in scope and apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Further, 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 drug manufacturers to report information related to payments or other transfers of value provided to physicians and other health care providers and entities or marketing expenditures.

These federal and state laws may impact, among other things, our proposed sales, marketing and education programs. If our 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 us, we 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 our operations, any of which could adversely affect our ability to operate its business and our results of operations. To the extent that any of our 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 our pharmaceutical product candidates, some of our 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 permit 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, we may apply for restoration of patent term for one of our 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 we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive 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. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. While commercial payors often follow Medicare cover policy and payment limitations, coverage and reimbursement for products can differ significantly from payor to payor. 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. We 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. Our 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 us to maintain price levels sufficient to realize an appropriate return on our 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 our products, payors may elect to cover such therapies in lieu of our products and/or reimburse our products at a lower rate.

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 we receive 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 we expect 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 we receive 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. For example, 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;

- 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, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new transparency reporting requirements under the federal Physician Payments Sunshine Act, created under Section 6002 of the PPACA;
- a requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- 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; 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.

Since its enactment there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will continue to be additional challenges and amendments to it in the future.

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 and, due to subsequent legislative amendments, will remain in effect through 2025 unless additional congressional action is taken. 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. More recently, there have been several recent congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. 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 our 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 us 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 us.

**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. We make available free of charge on or through our websiteour annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

We have had no revenues in 2016, 2015 and 2014. All of our long-lived assets are located in the United States.

**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.

In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and, therefore, are subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We 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 our annual gross revenues exceed $1 billion, (ii) the date that we 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 our common stock that are held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter, (iii) the date on which we have 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 (a date which occurred in July 2014). At this time we expect to remain an "emerging growth company" for the foreseeable future.

We also qualify as a "smaller reporting company" and have the advantage of not being required to provide the same level of disclosure as larger public companies.

**Employees**

As of March 1, 2017, we had 22 full-time employees, 7 of whom hold Ph.D.s, 2 of whom hold M.D.s and 3 of whom hold a Masters degree in relevant areas of expertise.

**Executive Officers of Registrant**

As of March 1, 2017, 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. | 69 | President, Chief Executive Officer & Director |
| Sujal Shah | 43 | Chief Financial Officer |
| Pol Boudes, M.D. | 59 | Chief Medical Officer |
| Robert L. Martin, Ph.D. | 54 | Senior Vice President, Manufacturing and Nonclinical Development |
| Charles A. McWherter, Ph.D. | 61 | Senior Vice President, Chief Scientific Officer |
| Patrick J. O'Mara | 55 | Senior Vice President, Business Development |
| Kirk Rosemark | 52 | Vice President, Regulatory Affairs and Quality Assurance |

**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** has served as our Chief Financial Officer since December of 2013. Prior to that he served as a consultant and acting Chief Financial Officer for us from June 2012 to December 2013. 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 and M.S. and B.S. degrees in Biomedical Engineering from Northwestern University.

**Pol Boudes, M.D.** has served as our Chief Medical Officer since April 2014. Prior to joining CymaBay, Dr. Boudes was Chief Medical Officer at Amicus Therapeutics, from 2009 to 2013 where he was responsible for clinical development, pharmacology, medical affairs, regulatory 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 Dr. Boudes 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.

**Robert L. Martin, Ph.D.,** has served as our Senior Vice President, Manufacturing and Nonclinical Development since April 2015. Previously, he served as our Vice President of Nonclinical Development and Project Management from 2008 to 2015. Dr. Martin served as our Sr. Director of Preclinical Development and Project Management from 2006 to 2008 and our Director of Preclinical Development and Project Management from 2004 to 2006. From 1994 to 2004, Dr. Martin served in various positions with Roche Palo Alto, a division of F. Hoffman-La Roche Ltd. Dr. Martin obtained his Ph.D. in Biochemistry from the University of California, Davis.

**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.

**Patrick O'Mara** has served as our Senior Vice President, Business Development since January 2017. Previously he served as our Vice President, Business Development from 2006 through 2016. He served as our Sr. Director of Business Development, from 2004 to 2006, our Director of Business Development from 2000 to 2004 and our Manager of Business Development from 1997 to 2000. Mr. O'Mara served as our Manager of Laboratory Operations from 1991 to 1997. Mr. O'Mara received a B.A. in Biochemistry from the University of California, Berkeley.

**Kirk Rosemark** has served as our Vice President Regulatory Affairs and Quality Assurance since April 2015. Prior to joining CymaBay Mr. Rosemark held the position of Vice President Regulatory Affairs and Quality Assurance at Exelixis, Inc. from 2003 to 2014, where he was responsible for all regulatory affairs and quality assurance functions supporting both development and marketed products. He served in the same capacity at NeoPharm Inc from 2001 to 2003. Prior to that, Mr. Rosemark held various positions of increasing responsibility within the Regulatory Affairs and Quality Assurance department at Solvay Pharmaceuticals, Inc., Ciba Vision and Bausch & Lomb Pharmaceuticals, Inc. Mr. Rosemark obtained a B.S. in Chemistry from Cleveland State University.

**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 incurred significant net losses in each year since our inception, including a net loss of approximately $26.7 million and $15.5 million for the years ended December 31, 2016, and 2015, respectively. We anticipate that we will continue to incur significant losses for the foreseeable future, and we may never achieve or maintain profitability. As of December 31, 2016, we had cash, cash equivalents and marketable securities of approximately $17.0 million. We believe that these funds, which were obtained through recent equity and debt financings, together with additional proceeds of approximately $14.4 million received from financings and license agreements in January and February of 2017, will allow us to continue operation through at least the next twelve months. We currently believe that we will need to raise additional capital to continue our operations thereafter. 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 increase in connection with our ongoing activities, particularly as we advance development of our lead clinical product candidate seladelpar (MBX-8025).

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

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

- the rate of progress and cost of our clinical studies, including in particular the Phase 2 studies of seladelpar;
- the extent to which we receive the milestone payments under our licensing agreement with Kowa;
- the extent to which we are able to out-license arhalofenate outside of the United States;
- the need for additional or expanded clinical studies;
- the rate of progress and cost of our Chemistry, Manufacturing and Control development, registration and validation program;
- the timing, economic and other terms of any licensing, collaboration or other similar arrangement into which we may enter;
- the costs and timing of seeking and obtaining FDA and other regulatory approvals;
- the extent of our other development activities;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the effect of competing products and market developments.

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

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

In late December 2016, we entered into an exclusive licensing agreement with Kowa Pharmaceuticals America, Inc., or Kowa, for the development and commercialization of arhalofenate in the U.S. (including all possessions and territories). The terms of our licensing agreement with Kowa provide them with exclusive authority over the development and commercialization plans for arhalofenate in the U.S. and the execution of those plans. We have no effective influence over those plans and are heavily dependent on Kowa's decision making. The licensing agreement provides that we will receive potential milestone payments of up to $10 million based on the initiation of specific development activities, and are eligible to receive up to an additional $190 million in payments based upon the achievement of additional development and sales milestones. We are also eligible to receive tiered, double digit royalties on future sales of arhalofenate products.

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

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

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

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

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

- the performance of Kowa under our licensing agreement, including whether development milestones and regulatory approvals regarding arhalofenate are achieved;
- our ability to out-license arhalofenate in jurisdictions outside of the United States;

- obtaining favorable results for and advancing the development of seladelpar; and
- generating a pipeline of product candidates.

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

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

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

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

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. In July 2015, we completed the issuance of 8,188,000 shares of our common stock at $2.81 per share and in February 2017, we completed the issuance of 5,181,348 shares of our commons stock at $1.93 per share in underwritten public offerings. Also, in January 2017, we issued 124,100 shares at $2.48 per share under our at-the-market facility. 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. For example, in December 2016 we entered into an agreement to license our right to develop and commercialize arhalofenate for the treatment of gout in the United States in exchange for a $5.0 million upfront payment and will receive potential milestone payments of up to $10 million based on the initiation of specific development activities, and are eligible to receive up to an additional $190 million in payments based upon the achievement of additional development and sales milestones and tiered, double digit royalties on any product sales. If we are unable to expand our operations or otherwise capitalize on our business opportunities, our business, financial condition and results of operations could be materially adversely affected and we may not be able to meet our debt service obligations. If we are unable to raise

additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts, or grant others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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

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

For as long as we continue to be an emerging growth company, we do intend to take advantage of certain other exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, 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 (a date which occurred in July 2014).

## Risks Related to Clinical Development and Regulatory Approval

***We depend on the success of our product candidates, in particular seldelpar, which is still under clinical development and we may not obtain regulatory approval or successfully commercialize this product candidate.***

We have not marketed, distributed or sold any products. The success of our business depends upon our ability to develop and commercialize our product candidates, including seladelpar, which has completed five Phase 1 and two Phase 2 clinical trials. There is no guarantee that our clinical trials will be completed or, if completed, will be successful. In March 2016, we completed a second Phase 2 clinical study for seladelpar in patients with homozygous familial hypercholestorolemia (HoFH). In November 2015, we initiated enrollment in a Phase 2 clinical study of seladelpar for patients with PBC. The success of seladelpar 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 for seladelpar in target indications in addition to those already obtained;

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

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

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

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

Seven clinical studies with seladelpar and five clinical studies with MBX-2982 have been completed. However, we have never conducted a Phase 3 clinical trial, and 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 seladelpar. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed satisfactorily through preclinical studies and initial clinical testing. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience, have suffered significant setbacks in Phase 3 clinical development, even after seeing promising results in earlier clinical trials.

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

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the clinical study protocol may require one or more amendments delaying study completion;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate or subjects may drop out of these clinical trials at a higher rate than we anticipate;

- clinical investigators or study subjects fail to comply with clinical study protocols;
- trial conduct and data analysis errors may occur, including, but not limited to, data entry and/or labeling errors;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our clinical trial materials or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators to suspend or terminate the trials.

We expect our research and development expenses to increase in connection with our ongoing activities, particularly as we undertake additional clinical trials of our other product candidates, seladelpar and MBX-2982. We also will need to raise substantial additional capital in the future to complete the development and commercialization of seladelpar, as well as MBX-2982 for which we currently have no planned clinical trials. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds required to complete research and development and commercialize our products under development.

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

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

We commenced clinical trials of seladelpar for the indications for which we currently are pursuing, including PBC and HoFH and seladelpar may not be demonstrated to be effective in treatment of these or other indications we may target. For instance, in May 2016, we announced results from a Phase 2 clinical study of seladelpar in patients with primary biliary cholangitis (PBC). We made the decision to discontinue the study early after review of safety and efficacy data demonstrated clear proof-of-concept and need for further dose reduction to optimize clinical safety and efficacy. In December 2016, we initiated a dose-ranging Phase 2 trial of seladelpar at lower doses in patients with PBC. In March 2016, we completed a Phase 2 clinical study evaluating seladelpar in 13 patients with HoFH. However, as a result of the variability in responses observed in this study, including a number of patients that did not experience a decrease in LDL-C, we believe additional proof-of-concept data would be warranted before determining whether or not to advance to a registration study of seladelpar in patients with HoFH. Although we believe that seladelpar may be beneficial to address the diseases for which we are considering redirecting its development, there is no guarantee that seladelpar will prove to be safe or efficacious in the treatment of these diseases, or that we will be able to obtain regulatory approval for these indications. The results of these clinical studies and other nonclinical studies may determine whether the benefits perceived from the use of seladelpar would outweigh the risks perceived from treatment with seladelpar.

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

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

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

- inability to raise funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA or other regulatory authorities on final trial design;
- imposition of a clinical hold following 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 seladelpar, is delayed for any of the above reasons, our development costs may increase, the approval process could be delayed, any periods during which we may have the exclusive right to commercialize our product candidates may be reduced and our competitors may bring products to market before us. Any of these events could impair our ability to generate revenues from product sales and impair our ability to generate regulatory and commercialization milestones and royalties, all of which could have a material adverse effect on our business.

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

In May 2016, we announced results from a Phase 2 clinical study of seladelpar in patients with primary biliary cholangitis (PBC). During the course of this trial three cases of asymptomatic, reversible transaminase elevations occurred, and we made the decision to discontinue the study early after review of safety and efficacy data demonstrated a need for further dose reduction to optimize clinical safety and efficacy. The emergence of adverse events (AEs) caused by seladelpar in future studies, including at lower doses, could cause us, other reviewing entities, clinical study sites or regulatory authorities to interrupt, delay or halt clinical studies and could result in the denial of regulatory approval. There is also a risk that our other product candidates may induce AEs, many of which may be unknown at this time. If an unacceptable frequency and/or severity of AEs are reported in our clinical trials for our product candidates, our ability to obtain regulatory approval for product candidates, including seladelpar, may be negatively impacted.

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

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution in a form of a risk evaluation and mitigation strategy (REMS);
- regulatory authorities may require the addition of labeling statements, such as 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 obtained orphan drug designation for some of the targeted indications for seladelpar but not all possible indications for which we may seek approval and we may not be able to obtain or maintain orphan designation or obtain the benefits associated with orphan drug status, including market exclusivity.***

Regulatory authorities in some jurisdictions, including the United States and the European Union, or EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, as amended, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA or the European Medicines Agency, or EMA, from approving another marketing application for the same drug for that time period. The applicable period is seven years in the United States and ten years in the European Union. The EU exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. In addition, the orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process. Also, regulatory approval for any product candidate may be withdrawn and other candidates may obtain approval before us.

We have obtained orphan-drug designations for seladelpar for the treatments of HoFH and Frederickson Type I or V hyperlipoproteinemia. That exclusivity, or any other orphan exclusivity we may receive for another produc candidate or indication, may not effectively protect the candidate from competition because: different drugs can be approved for the same condition; the same drugs can be approved for different indications and prescribed off-label; and the first entity with an orphan drug designation to receive regulatory approval for a particular indication will receive marketing exclusivity. If one of our product candidates that receives an orphan drug designation, including seladelpar, is approved for a particular indication or use within the rare disease or condition, the FDA may later approve the same product for additional indications or uses within that rare disease or condition that are not protected by our exclusive approval. Even after an orphan drug is approved, the FDA can subsequently approve another drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer in a substantial portion of the target population, more effective or makes a major contribution to patient care.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

***Even if we obtain FDA approval for seladelpar or any of our other product candidates in the U.S., we may never obtain approval for or commercialize seladelpar or any of our other product candidates 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 health care professionals, customers and payors will be subject to applicable anti-kickback, fraud and abuse and other health care laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

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

- the federal health Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal health care programs such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- HIPAA, as amended by HITECH, imposes criminal and civil liability for executing a scheme to defraud any health care benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services;
- the federal transparency requirements under the PPACA, commonly referred to as the Physician Payments Sunshine Act, require manufacturers of drugs, devices, biologics and medical supplies to report to the Centers for Medicare and Medicaid Services (CMS) payments and other transfers of value provided to physicians and teaching hospitals and ownership and investment interests held by physicians and other healthcare providers and their immediate family members in certain manufacturers and group purchasing organizations; and

- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving health care items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

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

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

In the 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.

For example, in March 2010, the PPACA was enacted to broaden access to health insurance, reduce or constrain the growth of health care spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The PPACA revises the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the new law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. New provisions affecting compliance have also been enacted, which may affect our business practices with health care practitioners. Since its enactment there have been judicial and Congressional challenges to certain aspects of the PPACA, and we expect there will be additional challenges and amendments to it in the future. Although the full effect of the PPACA remains uncertain, it appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Further, other legislative changes have been adopted since the PPACA was enacted, such as the Budget Control Act of 2011 and the American Taxpayer Relief Act of 2012, which have resulted in reduced reimbursement under the Medicare program.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. In addition, there have been several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. We are not sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be.

## Risks Related to Our Reliance on Third Parties

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

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

The facilities used by our contract manufacturers to manufacture the 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 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 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 seladelpar, and any disruption in the chain of supply may cause delay in developing and commercializing of seladelpar.***

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 our products. An alternative vendor would need to be qualified through a supplemental registration which would be expensive and could result in further delay. The FDA or other regulatory agencies outside of the 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 our products, and cause us to incur additional costs. Furthermore, if our suppliers fail to deliver the required commercial quantities of active pharmaceutical ingredient on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, the supply chain for our products may be delayed, which could inhibit our ability to generate revenues.

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

We expect to increase the manufacturing batch sizes of our products in preparation of late stage clinical development and commercial supplies. As the processes are scaled up they may reveal manufacturing challenges

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

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

- the inability to meet our product specifications 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 our product candidates, as well as the execution of nonclinical studies. We control only certain aspects of our CSPs' activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CSPs does not relieve us of our regulatory responsibilities.

We and our CSPs are required to comply with the FDA's guidance, which follows the International Conference on Harmonization Good Clinical Practice (ICH GCP), which are regulations and guidelines enforced by the FDA for all of our product candidates in clinical development. The FDA enforces the ICH GCP through

periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CSPs fail to comply with the ICH GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. Our CSPs are not our employees, and we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and nonclinical programs. These CSPs may also have relationships with other entities, including our competitors, for whom they may also be conducting clinical studies, or other drug development activities 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 our product candidates. As a result, our financial results and the commercial prospects for our product candidates that we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

## Risks Related to Commercialization of Our Product Candidates

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

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

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

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

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

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

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

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

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

***If we obtain approval to commercialize any products outside of the 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 seladelpar. We expect that we will be subject to additional risks related to international operations, including the following:

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;

- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the 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 our own, our commercial opportunities will be negatively impacted.***

The life sciences industry is highly competitive, and we face significant competition from other pharmaceutical, biopharmaceutical and biotechnology companies and possibly from academic institutions, government agencies and private and public research institutions that are researching, developing and marketing products designed to address 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, seladelpar and our other product candidates, which could make it difficult for us to sell our products profitably.***

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

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

The availability of generic treatments may also substantially reduce the likelihood of reimbursement for any future products, including seladelpar. The application of user fees to generic drug products will likely expedite the approval of additional generic drug treatments. We expect to experience pricing pressures in connection with the sale of seladelpar and any other product candidate that we develop, due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes.

In addition, there may be significant delays in obtaining reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or health authorities in other countries. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government health care programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the 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 seladelpar, it could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

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

Any regulatory approvals that we or potential collaboration partners receive for seladelpar or future product candidates, may also be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing studies. In addition, even if approved, the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for any product will be subject to extensive and ongoing regulatory requirements. The subsequent discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, may result in restrictions on the marketing of the product, and could include withdrawal of the product from the market. Depending on any safety issues associated with our product candidates that are approved, the FDA may require a REMS, thereby imposing certain restrictions on the sale and marketability of such products or additional post-marketing requirements.

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

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

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

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

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

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

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

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

## Risks Related to Our Intellectual Property

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

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

1) We rely on an exclusive license to certain patents and know-how from Janssen Pharmaceutical NV (Janssen NV), which include seladelpar and certain other PPARd compounds (the "PPARd Products"). Under the exclusive license with Janssen NV we have full control and responsibility over the research, development and

registration of any PPARd Products and are required to use diligent efforts to conduct all such activities. If we fail to comply with our obligations under our agreement with Janssen NV, including our obligations to expend more than a de minimus amount of effort and resources on the research and/or development of at least one PPARd product, to make any payment called for under the agreement, not to disclose any non-exempt confidential information related to the agreement, or to use diligent efforts to promote, market and sell any PPARd Product under the agreement, such action would constitute a default under the agreement and Janssen NV may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license, including in the case of the Janssen NV license, seladelpar, which would have a materially adverse effect on our business.

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

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

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

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

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

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

Periodic maintenance fees on any issued patent are due to be paid to the U.S. PTO and foreign patent agencies in several stages over the lifetime of the patent. The U.S. PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or

complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors that control the prosecution and maintenance of our licensed patents fail to maintain the patents and patent applications covering our product candidates, we may lose our rights and our competitors might be able to enter the market, which would have a material adverse effect on our business.

## Risks Related to Our Business Operations and Industry

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

We are highly dependent on principal members of our executive team listed under "Business — Executive Officers of Registrant" of this Annual Report on Form 10-K. 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, 2017, we had 22 full-time employees. As our company matures, we expect to expand our employee base to increase our managerial, clinical, scientific and engineering, operational, sales, and marketing teams. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

***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.

***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, in February 2017, we completed the issuance of 5,181,348 shares of our common stock at $1.93 per share in an underwritten public offering for the net proceeds to us of $9.2 million, in July 2015, we completed the issuance of 8,188,000 shares of our common stock at $2.81 per share in an underwritten public offering for net proceeds to us of $21.1 million, and in November 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 $4.5 million during the period January 1, 2015, through January 31, 2017. If in the future we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. These sales may also result in new investors gaining rights superior to our existing stockholders. Pursuant to our equity incentive plans, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares available for future grant under our equity incentive plans as of March 1, 2017, was 652,687 shares.

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

We do not anticipate paying cash dividends in the future. As a result, only appreciation of the price of our common stock, which may never occur, will provide a return to stockholders. Investors seeking cash dividends should not invest in our common stock. In addition, our ability to pay cash dividends is currently prohibited without the prior consent of the lender pursuant to the terms of our 2015 loan and security agreements.

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

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

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

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

## Item 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. 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 21, 2017, the last reported sale price of our common stock on the NASDAQ Capital Market was $3.91 per share. As of March 1, 2017, there were approximately 297 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, 2015 | High | Low |
|---|---|---|
| First Quarter | $13.39 | $6.75 |
| Second Quarter | $ 7.03 | $2.64 |
| Third Quarter | $ 3.31 | $1.61 |
| Fourth Quarter | $ 2.27 | $1.21 |

| Year Ended December 31, 2016 | High | Low |
|---|---|---|
| First Quarter | $1.86 | $0.82 |
| Second Quarter | $3.04 | $1.33 |
| Third Quarter | $2.59 | $1.48 |
| Fourth Quarter | $2.39 | $1.15 |

**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.

### 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," "potential," "seek," "target,"*

*"goal," "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 specialty and orphan diseases with high unmet medical need. Our two key clinical development candidates are seladelpar and arhalofenate.

We are currently developing seladelpar (MBX-8025) for the treatment of primary biliary cholangitis (PBC), an autoimmune disease that causes progressive destruction of the bile ducts in the liver. Seladelpar is a potent and selective agonist of PPARd, a nuclear receptor that regulates genes important for lipid, bile acid/sterol and glucose metabolism and for inflammation in liver and muscle. In May 2016, we announced results from a Phase 2 clinical study of seladelpar in patients with PBC. The study was intended to enroll approximately 75 patients with PBC who had an inadequate response to ursodiol and randomize them to receive either placebo or seladelpar (either 50 mg or 200 mg) once-daily for 12 weeks. Despite the occurrence of three cases of asymptomatic, reversible transaminase elevations (two in the 200 mg and one in the 50 mg groups), data from 35 patients evaluated for efficacy demonstrated that treatment with seladelpar resulted in statistically significant reductions in the primary endpoint of serum alkaline phosphatase (ALP). The mean decreases from baseline in ALP for the 50 and 200 mg dose groups were 53% and 63%, respectively, vs. 2% for placebo ($p < 0.0001$ for both). Based on results from a number of published studies, lower levels of ALP have been shown to correlate with a significant reduction in adverse clinical outcomes for PBC patients including liver transplant and/or death. All patients who received seladelpar treatment for 12 weeks (three on 50 mg and two on 200 mg) had their ALP values restored to within the normal range. The study was discontinued early after review of safety and efficacy data demonstrated proof-of-concept for activity on cholestatic biomarkers and had identified the need to reduce the dose in order to optimize for clinical safety and efficacy. In October 2016, seladelpar received European Medicines Agency (EMA) PRIority MEdicines (PRIME) designation for the treatment of PBC. The U.S. Food and Drug Administration (FDA) granted orphan drug designation to seladelpar for the treatment of PBC in November 2016. In December 2016, we initiated a dose-ranging Phase 2 study of seladelpar at lower daily doses of 5 and 10 mg in patients with PBC.

In March 2016, we announced results from a Phase 2 clinical study evaluating seladelpar in 13 patients with homozygous familial hypercholesterolemia (HoFH), a rare, life-threatening, genetic disease characterized by marked elevations in plasma levels of low density lipoprotein (LDL-C) leading to severe atherosclerosis and the development of premature cardiovascular diseases. Five patients in this study experienced what we believe was a clinically meaningful maximal decrease in LDL-C of greater than 20% with three of them having decreases greater than 30%. However, given the variability in responses observed in this study, including a number of patients that did not experience a decrease in LDL-C, we believe additional proof-of-concept data would be warranted before determining whether or not to advance to a registration study of seladelpar in patients with HoFH.

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

In late December 2016, we entered into an exclusive licensing agreement with Kowa Pharmaceuticals America, Inc. (Kowa) for the development and commercialization of arhalofenate in the U.S. (including all its possessions and territories). Under the terms of the agreement, we received an up-front payment of $5 million in January 2017, and will receive potential milestone payments of up to $10 million based on the initiation of specific development activities, and are eligible to receive up to an additional $190 million in payments based upon the achievement of additional development and sales milestones. We are also eligible to receive tiered, double digit royalties on future sales of arhalofenate products. Kowa will be responsible for all development and commercialization costs. We retain full development and commercialization rights for the rest of the world and intend to partner arhalofenate in geographies outside the U.S. and its possessions and territories.

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

**Equity Financings**

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

On November 7, 2014, we filed a $100 million registration statement on Form S-3 with the SEC, which registration statement includes an at-the-market facility (ATM) to sell up to $25 million of common stock under the registration statement. As of December 31, 2016, we have sold shares of common stock under the ATM with aggregate net proceeds to us of $4.3 million.

On July 27, 2015, pursuant to our shelf registration statement on Form S-3, we completed the issuance of 8.2 million shares of our common stock at $2.81 per share which we refer to as our 2015 public offering. Net proceeds to us in connection with the 2015 public offering were approximately $21.1 million after deducting underwriting discounts, commissions and other offering expenses.

During January 2017, we sold an additional 124,100 shares of our common stock for net proceeds of $158,000 under the ATM.

On February 2, 2017, pursuant to our shelf registration statement on Form S-3, we completed the issuance of 5.2 million shares of our common stock at $1.93 per share which we refer to as our 2017 public offering. Net proceeds to us in connection with the 2017 public offering were approximately $9.2 million after deducting underwriting discounts, commissions and other offering expenses.

**Critical Accounting Policies and Use of Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (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.

***Revenue Recognition***

We recognize revenue when all four of the following criteria have been met: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or services have been rendered, (iii) the fee is fixed or determinable and (iv) collectability is reasonably assured. Revenue under collaboration and license arrangements is recognized based on the performance requirements of the contract. Determinations of whether persuasive evidence of an arrangement exists and whether delivery has occurred or services have been rendered are based on management's judgments regarding the fixed nature of the fees charged for deliverables and the collectability of those fees.

We generate revenue from collaboration and license agreements for the development and commercialization of products. Collaboration and license agreements may include non-refundable upfront license fees, contingent consideration payments based on the achievement of defined collaboration objectives and royalties on sales of commercialized products.

Our performance obligations under the collaboration and license agreement may include the license or transfer of intellectual property rights, obligations to provide research and development services, delivery of related materials and obligations to participate on certain development and/or commercialization committees with the collaborators.

If we determine that multiple deliverables in an arrangement exist, the consideration is allocated to one or more units of accounting based upon the relative-selling-price of each element in an arrangement. The relative-selling-price used for each deliverable will be based on vendor-specific objective evidence, if available, third-party evidence if vendor-specific objective evidence is not available, or estimated selling price if neither vendor-specific or third-party evidence is available. We identify deliverables at the inception of the arrangement. Each deliverable is accounted for as a separate unit of accounting if both of the following criteria are met: (1) the delivered item or items have value to the customer on a standalone basis and (2) for an arrangement that includes a general right of return relative to the delivered items, delivery or performance of the undelivered items is considered probable and substantially in our control. Non-refundable upfront payments received and allocated to separate units of accounting are recognized as revenue when the four basic revenue recognition criteria, mentioned above, are met for each unit of accounting.

We recognize payments that are contingent upon achievement of a substantive milestone in their entirety in the period in which the milestone is achieved. Milestones are defined as events that can only be achieved based on our performance and there is substantive uncertainty about whether the event will be achieved at the inception of the arrangement. Events that are contingent only on the passage of time or only on counterparty performance are not considered milestones subject to this guidance. Further, the amounts received must relate solely to prior performance, be reasonable relative to all of the deliverables and payment terms within the agreement and commensurate with our performance to achieve the milestone after commencement of the agreement. Any contingent payment that becomes payable upon achievement of events that are not considered substantive milestones are allocated to the units of accounting previously identified at the inception of an arrangement when the contingent payment is received and revenue is recognized based on the revenue recognition criteria for each unit of accounting.

***Research and Development Expenses and Related Prepayments and Accruals***

As part of the process of preparing our financial statements, we are required to estimate certain research and development expenses. This process involves reviewing contracts, reviewing the terms of our license agreements, communicating with our vendors and 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 either when we have prepaid or when we have not yet been invoiced or otherwise notified of actual cost. Although certain of our vendors require us to prepay in advance of services rendered, the majority of our service providers invoice us monthly in arrears for services performed. We make estimates of prepayments to amortize or expenses to be accrued as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. Examples of estimated amortized or 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 either amortizing or 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 related prepayment or 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, 2016, and 2015.

***Stock-Based Compensation***

We measure employee and director stock-based compensation cost at the grant date, based on the estimated fair-value of the awards, and we recognize as an expense the portion that is ultimately expected to vest as an expense over the related vesting periods, net of estimated forfeitures. We estimate the grant date fair-value based of stock options using the Black-Scholes option-pricing model and recognize compensation expense over the service period using the straight-line attribution method. For performance-based stock options, we evaluate the probability of achieving each performance-based condition at each reporting date. We begin to recognize the expense when it is deemed probable that a performance-based condition will be met using the accelerated attributed method over the requisite service period.

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. We estimate expected volatility based on our own historical volatility supplemented by a review of historical volatilities of industry peers. We have, due to insufficient historical data, used the “simplified method” to determine the expected life of stock options granted with a service condition. 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.

We account for stock-based compensation arrangements with non-employees using a fair value approach. The fair value of these options is measured using the Black-Scholes option pricing model reflecting the same

assumptions as applied to employee options in each of the reported periods, other than the expected life, which is assumed to be the remaining contractual life of the option. The compensation costs of these arrangements are subject to remeasurement over the vesting terms as earned.

***Warrant Liabilities***

We have issued freestanding warrants to purchase shares of our common stock. These freestanding warrants are classified as liabilities in the balance sheet and remeasured at each reporting period at fair value as they contain terms for redemption of the underlying security that are outside our control. We use a binomial lattice option pricing model to estimate the fair value of warrants. Significant inputs to this model include our stock price, the warrant exercise price, and other inputs that management is required to estimate including key strategic initiatives, probability of success related to those initiatives, change in our stock price based on the outcome of the initiatives, expected volatility and expected term. These inputs are inherently subjective and require significant analysis and judgment to develop. We re-measure the fair value of all warrants at each financial reporting date with any changes in fair value being recognized as a component of other income (expense), net 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 income from operations. As of December 31, 2016, we have an accumulated deficit of $423.0 million, primarily as a result of expenditures for research and development and general and administrative expenses. While we will generate revenue from our license arrangement with Kowa and may in the future generate revenue from a variety of other sources, including additional milestone payments from Kowa and license fees and milestone payments in connection with other strategic partnerships, arhalofenate and seladelpar are at a mid-level stage of development and our other product candidates are at the early stage of development and may never be successfully developed or commercialized. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future and there can be no assurance that we will ever generate sufficient revenue to achieve and sustain profitability. Our results of operations for 2016 and 2015 are presented below:

| | Year Ended December 31, | | |
|---|---|---|---|
| *($ in thousands)* | **2016** | **2015** | **Variance** |
| Operating expenses: | | | |
| Research and development | $ 15,941 | $ 17,026 | $ (1,085) |
| General and administrative | 9,645 | 8,871 | 774 |
| Loss from operations | (25,586) | (25,897) | 311 |
| Interest expense, net | (1,161) | (753) | (408) |
| Other income, net | 76 | 11,121 | (11,045) |
| Net loss | $(26,671) | $(15,529) | $(11,142) |

***Research & Development Expenses***

Conducting research and development is central to our business model. For the years ended December 31, 2016 and 2015, research and development expenses were $15.9 million and $17.0 million, respectively. Research and development expenses are detailed in the table below:

| | Year Ended December 31, | |
|---|---|---|
| ($ in thousands) | 2016 | 2015 |
| Seladelpar Phase 2 clinical studies | $ 6,029 | $ 2,812 |
| Seladelpar Drug manufacutring & toxicity studies | 3,051 | 3,830 |
| Seladelpar Other studies | 54 | 152 |
| Arhalofenate Gout Phase 2b randomized study | 32 | 1,313 |
| Arhalofenate Gout Febuxostat combo study | 25 | 165 |
| Arhalofenate Gout Drug manufacturing | 495 | 3,387 |
| Other Projects | 62 | 38 |
| **Total Project Costs** | 9,748 | 11,697 |
| Internal Research and Development Costs | 6,193 | 5,329 |
| **Total Research and Development** | $15,941 | $17,026 |

Our project costs consist primarily of:

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

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

Total project costs decreased by $2.0 million to $9.7 million from $11.7 million for the years ended December 31, 2016, and 2015, respectively. Project costs for the year ended December 31, 2016 primarily consist of PBC Phase 2 clinical trial expenses as well as drug manufacturing and toxicology studies for seladelpar. Project costs for the year ended December 31, 2015 primarily consisted of PBC Phase 2 clinical trial expenses and arhalofenate Phase 2 clinical trial expenses as well as drug manufacturing costs related to registration batch production and other manufacturing process development activities for arhalofenate. The decrease in project costs for year ended December 31, 2016 as compared to December 31, 2015 was primarily due to completion of arhalofenate Phase 2 clinical trials in 2015, partially offset by higher costs for PBC Phase 2 clinical trials due to the initiation of our second study with lower doses of seladelpar. Internal research and development cost increased by $0.9 million for year ended December 31, 2016 as compared to December 31, 2015, primarily due to higher employee compensation related expenses to support our clinical development activities.

We expect to continue to incur substantial expenses related to our development activities for the foreseeable future as we continue product development and initiate additional clinical studies for seladelpar. Since product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later stage clinical trials, we expect that our research and development expenses will increase in the future despite the fact that we are no longer incurring development costs for arhalofenate. In addition, if our product development efforts are successful, we expect to incur substantial costs to prepare for potential Phase 3 clinical trials and activities.

***General and Administrative Expenses***

General and administrative expenses consist principally of personnel-related costs, professional fees for legal, consulting, audit services, rent and other general operating expenses not otherwise included in research and development. General and administrative expenses increased by $0.7 million, to $9.6 million from $8.9 million, for the years ended December 31, 2016 and 2015, respectively, primarily as a result of higher employee compensation and consulting expenses related to our licensing agreement with Kowa. For the next several quarters, we anticipate general and administrative expenses will remain relatively consistent with current levels.

***Interest Expense, Net***

Interest expense, net consists of interest expense due to our loan facility partially offset by interest income from our marketable securities. Interest expense, net increased by $0.4 million, to $1.2 million from $0.8 million, for the years ended December 31, 2016 and 2015, respectively, primarily as a result of the refinancing of our loan facility, which we completed in the third quarter of 2015. The refinanced loan facility resulted in a higher loan balance and correspondingly higher interest expense.

***Other Income, Net***

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

Other income, net reflected a gain of $76,000 and $11.1 million for the years ended December 31, 2016 and 2015, respectively, in each case due to the remeasurement of our warrant liabilities at fair value. During the year ended December 31, 2016, the gain recognized was due primarily to a reduction in the expected term and volatility of our investor warrants which are approaching expiration in September 2018. The changes in these assumptions offset the impact to the model of an increase in the price of our common stock from $1.69 at December 31, 2015, to $1.73 at December 31, 2016. During the year ended December 31, 2015, the gain recognized was due to a decrease in the price of our common stock from $9.83 at December 31, 2014, to $1.69 at December 31, 2015.

***Income Taxes***

As of December 31, 2016, we had federal net operating loss carryforwards of $229.1 million and state net operating loss carryforwards of $175.1 million to offset future taxable income, if any. In addition, we had federal research and development tax credit carry forwards of $7.7 million and state research and development tax credit carryforwards of $6.3 million. If not utilized, the federal net operating loss and tax credit carryforwards will expire beginning in 2024 through 2036 and the state net operating loss carryforwards will expire beginning in 2017 through 2036. 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, 2016, we recorded a 100% valuation allowance against our deferred assets of approximately $121.6 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. As of December 31, 2016, cash, cash equivalents and marketable securities totaled $17.0 million, a decrease of $24.5 million, from December 31, 2015, which is consistent with our expectation to finance our operations.

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

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

On July 27, 2015, pursuant to our shelf registration statement on Form S-3, we completed the issuance of 8.2 million shares of our common stock at $2.81 per share in an underwritten public offering. Net proceeds to us in connection with this offering were approximately $21.1 million after deducting underwriting discounts, commissions and other offering expenses.

On January 12, 2017, we received a $5.0 million upfront payment pursuant to our exclusive licensing agreement with Kowa. for the development and commercialization of arhalofenate in the U.S.

During January 2017, we sold an additional 124,100 shares of our common stock for net proceeds of $158,000 under our ATM.

On February 2, 2017, pursuant to our shelf registration statement on Form S-3, we completed the issuance of 5.2 million shares of our common stock at $1.93 per share which we refer to as our 2017 public offering. Net proceeds to us in connection with the 2017 public offering were approximately $9.2 million after deducting underwriting discounts, commissions and other offering expenses.

***2013 Term Loan Facility***

In the 2013 financing, we entered into 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, the first $5 million tranche of which was made available to us as of September 30, 2013 bearing interest at a rate equal to 8.75% per annum. The remaining $5 million, referred to as the second tranche, became available to us for draw down upon our February 24, 2015, announcement of the achievement of positive Phase 2b study data in arhalofenate and remained available to us until June 30, 2015. We did not draw down on the $5 million second tranche before that portion of the loan facility expired on June 30, 2015.

***2015 Term Loan Facility***

On August 7, 2015, we entered into a new Loan and Security Agreement pursuant to which we refinanced our 2013 term loan facility with Oxford Finance LLC and Silicon Valley Bank for an aggregate amount of up to $15 million, which we refer to as the 2015 term loan facility. The first $10 million tranche of this new loan facility was made available to us immediately upon the closing and was used in part to retire all $4.1 million of our existing term loan debt outstanding on the closing date, and to settle closing costs with the lenders. The remaining $5 million, referred to as the second tranche, was available to us until March 31, 2016, for draw down upon the announcement of a qualified out-license or co-development arrangement for arhalofenate, our gout therapy drug candidate, which includes an upfront payment of not less than $35.0 million (the “second draw milestone”). The $5 million second tranche expired unused in March 2016 as the second draw milestone was not achieved.

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

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

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

The 2015 term loan facility contains customary representations and warranties and customary affirmative and negative covenants applicable to us, including, among other things, restrictions on dispositions, changes in business, management, ownership or business locations, mergers or acquisitions, indebtedness, encumbrances, distributions, investments, transactions with affiliates and subordinated debt. The representations and warranties contained in the 2015 loan facility were made only for purposes of such agreement and as of specific dates, were solely for the benefit of the parties to such agreement to allocate risk and may be subject to limitations agreed upon by the parties; accordingly, they should not be relied upon by investors as to assertions of factual matters. The 2015 term loan facility also includes customary events of default, including but not limited to the nonpayment of principal or interest, violations of covenants, material adverse change, attachment, levy, restraint on business, bankruptcy, material judgments and misrepresentations. Upon an event of default, the lenders may, among other things, accelerate the loans and foreclose on the collateral. As of December 31, 2016, we were in compliance with the terms of the term loan covenants and there were no events of default.

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

***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, | |
|---|---|---|
| | **2016** | **2015** |
| Net cash used in operating activities | $ (23,353) | $ (23,324) |
| Net cash provided by (used in) investing activities | 27,128 | (11,083) |
| Net cash (used in) provided by financing activities | (986) | 30,527 |
| Net increase (decrease) in cash and cash equivalents | $ 2,789 | $ (3,880) |

*Cash Flows from Operating Activities*

Net cash used in operating activities for the year ended December 31, 2016, was $23.4 million primarily due to a net loss of $26.7 million, offset by $2.5 million of stock-based compensation, changes in operating assets and liabilities of $0.3 million, and other noncash items of $0.5 million.

Net cash used in operating activities for the year ended December 31, 2015, was $23.3 million primarily due to a net loss of $15.5 million and change in fair value of our warrant liability of $11.1 million as a results of a decline in on our stock price, offset by $2.5 million of stock-based compensation, changes in operating assets and liabilities of $0.1 million, and other noncash items of $0.7 million.

*Cash Flows from Investing Activities*

Net cash provided by investing activities was $27.1 million for the year ended December 31, 2016, as a result of net maturities of marketable securities which were used to fund our ongoing drug development and other operating activities.

Net cash used in investing activities was $11.1 million for the year ended December 31, 2015, primarily due to net purchases of marketable securities as we sought to invest funds raised in our equity and debt financings.

*Cash Flows from Financing Activities*

Net cash used in financing activities was $1.0 million for the year ended December 31, 2016, due to scheduled repayments of principal on our facility loan.

Net cash provided by financing activities was $30.5 million for the year ended December 31, 2015, primarily as a result of proceeds from the 2015 facility loan and from our 2015 public offering, net of issuance costs. These cash inflows were offset by repayment of loan principal.

***Capital Requirements***

We have incurred operating losses since inception and had an accumulated deficit of $423.0 million at December 31, 2016. As of December 31, 2016, we had cash, cash equivalents and marketable securities of approximately $17.0 million. We believe that these funds, which were obtained through recent equity and debt financings, together with additional proceeds received from financings and license agreements in January and February of 2017 of approximately $14.4 million, will allow us to continue operation through at least the next twelve months. We expect to incur substantial expenditures in the future for the development and potential commercialization of our product candidates. Because of this, we expect our future liquidity and capital resource needs will be impacted by numerous factors, including but not limited to, the extent to which we receive milestone payments under our licensing agreement with Kowa, and the timing of initiation of planned clinical trials, such as our phase 2 trials to study the therapeutic benefits of seladelpar on patients with certain orphan diseases. We will therefore continue to require additional financing to develop our products and fund future operating losses and will seek funds through equity financings, debt, collaborative or other arrangements with corporate sources, or through other sources of financing. It is unclear if or when any such financing transactions will occur, on satisfactory terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. If adequate funds are not available to us, we may be required to reduce our development activities or limit or cease operations.

**Off Balance Sheet Arrangements**

As of December 31, 2016, 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, 2016:

| | Payments Due by Period | | | |
|---|---|---|---|---|
| *(In thousands)* | Total | Less than 1 Year | 1-3 Years | 3-5 Years |
| **Contractual Obligations** | | | | |
| Operating lease obligations | $ 450 | $ 222 | $ 228 | $ — |
| Facility term loan, including interest | 10,792 | 3,803 | 6,989 | — |
| Contractual Commitments | $11,242 | $ 4,025 | $ 7,217 | $ — |

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, 2016, under the terms of our agreements with these organizations, we are obligated to make future payments as services are provided of approximately $8.9 million. 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.

We have license milestone obligation payments that are not included in the table above because we cannot determine when or if the payments will occur. In the normal course of business, we enter into various firm purchase commitments and other contractual obligations which are cancelable within ninety days or less and are not included in the future contractual obligations table above.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

Not applicable.

**Item 8. Financial Statements and Supplementary Data**

The disclosure required in this Item 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*.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act, and the rules and regulations thereunder, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible 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, 2016.

*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.

*Changes in Internal Controls*.

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2016, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**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 2017 annual meeting of stockholders, or 2017 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 2017 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 — Information Regarding Committees of the Board of Directors — Nominating and Corporate Governance Committee" in our 2017 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 2017 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 2017 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.

We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this Code of Business Conduct and Ethics by posting such information on our website, at the address and location specified above.

**Item 11.** ***Executive Compensation***

Reference is made to the information to be included under the heading "Executive Compensation" in our 2017 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 2017 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 2017 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 2017 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 2017 Proxy Statement under the caption "Principal Accountant Fees and Services" in the proposal under the caption "Ratification of Selection of Independent Registered Public Accounting Firm" 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, 2016 and 2015, and the related statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2016. 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, 2016 and 2015, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Redwood City, California
March 23, 2017

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

| | December 31, | |
|---|---|---|
| | 2016 | 2015 |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 10,495 | $ 7,706 |
| Marketable securities | 6,499 | 33,774 |
| Prepaid expenses | 1,369 | 608 |
| Other current assets | 165 | 186 |
| Total current assets | 18,528 | 42,274 |
| Property and equipment, net | 77 | 64 |
| Other assets | 754 | 741 |
| Total assets | $ 19,359 | $ 43,079 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 899 | $ 1,008 |
| Accrued liabilities | 4,501 | 3,336 |
| Warrant liability | 1,145 | 1,220 |
| Facility loan | 2,700 | 509 |
| Accrued interest payable | 66 | 73 |
| Total current liabilities | 9,311 | 6,146 |
| Facility loan, less current portion | 6,098 | 8,799 |
| Other liabilities | 13 | 19 |
| Total liabilities | 15,422 | 14,964 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock, $0.0001 par value: 10,000,000 shares authorized; no shares issued and outstanding | — | — |
| Common stock, $0.0001 par value: 100,000,000 shares authorized; 23,447,003 and 23,447,003 shares issued and outstanding as of December 31, 2016 and December 31, 2015, respectively | 2 | 2 |
| Additional paid-in capital | 426,895 | 424,422 |
| Accumulated other comprehensive loss | (1) | (21) |
| Accumulated deficit | (422,959) | (396,288) |
| Total stockholders' equity | 3,937 | 28,115 |
| Total liabilities and stockholders' equity | $ 19,359 | $ 43,079 |

*See accompanying notes.*

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

| | Year Ended December 31, | |
|---|---|---|
| | 2016 | 2015 |
| Operating expenses: | | |
| Research and development | $ 15,941 | $ 17,026 |
| General and administrative | 9,645 | 8,871 |
| Total operating expenses | 25,586 | 25,897 |
| Loss from operations | (25,586) | (25,897) |
| Other income (expense): | | |
| Interest income | 176 | 160 |
| Interest expense | (1,337) | (913) |
| Other income, net | 76 | 11,121 |
| Net loss | $ (26,671) | $ (15,529) |
| Net loss | $ (26,671) | $ (15,529) |
| Other comprehensive income (loss): | | |
| Unrealized gain (loss) on marketable securities | 20 | (7) |
| Other comprehensive income (loss) | 20 | (7) |
| Comprehensive loss | $ (26,651) | $ (15,536) |
| Basic net loss per common share | $ (1.14) | $ (0.82) |
| Diluted net loss per common share | $ (1.14) | $ (0.83) |
| Weighted average common shares outstanding used to calculate basic net loss per common share | 23,447,003 | 18,900,473 |
| Weighted average common shares outstanding used to calculate diluted net loss per common share | 23,447,003 | 18,917,213 |

*See accompanying notes.*

**CymaBay Therapeutics, Inc.**
**Statements of Stockholders' Equity**
*(In thousands, except share and per share information)*

| | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Income (Loss) | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| Balances as of December 31, 2014 | 14,696,108 | $ 1 | $394,622 | $ (14) | $ (380,759) | $ 13,850 |
| Issuance of common stock upon exercise of warrants | 132,295 | — | 1,939 | — | — | 1,939 |
| Stock-based compensaton expense | — | — | 2,487 | — | — | 2,487 |
| Issuance of common stock, net of $2,028 issuance costs | 8,618,600 | 1 | 25,374 | — | — | 25,375 |
| Net loss | — | — | — | — | (15,529) | (15,529) |
| Net unrealized loss on marketable securities | — | — | — | (7) | — | (7) |
| Balances as of December 31, 2015 | 23,447,003 | $ 2 | $424,422 | $ (21) | $ (396,288) | $ 28,115 |
| Stock-based compensaton expense | — | — | 2,473 | — | — | 2,473 |
| Net loss | — | — | — | — | (26,671) | (26,671) |
| Net unrealized gain on marketable securities | — | — | — | 20 | — | 20 |
| Balances as of December 31, 2016 | 23,447,003 | $ 2 | $426,895 | $ (1) | $ (422,959) | $ 3,937 |

*See accompanying notes.*

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

| | Year Ended December 31, | |
|---|---|---|
| | 2016 | 2015 |
| **Operating activities** | | |
| Net loss | $ (26,671) | $ (15,529) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 29 | 22 |
| Stock-based compensation expense | 2,473 | 2,487 |
| Amortization of premium on marketable securities | 125 | 511 |
| Non-cash interest associated with debt discount accretion | 476 | 228 |
| Change in fair value of warrant liability | (75) | (11,121) |
| Changes in assets and liabilities: | | |
| Other current assets | 165 | 161 |
| Prepaid expenses | (761) | 1,383 |
| Other assets | (13) | (486) |
| Accounts payable | (109) | (1,077) |
| Accrued liabilities | 1,015 | (46) |
| Accrued interest payable | (7) | 143 |
| Net cash used in operating activities | (23,353) | (23,324) |
| **Investing activities** | | |
| Purchases of property and equipment | (42) | — |
| Purchases of marketable securities | (22,906) | (42,788) |
| Proceeds from maturities of marketable securities | 50,076 | 31,705 |
| Net cash provided by (used in) investing activities | 27,128 | (11,083) |
| **Financing activities** | | |
| Proceeds from facility loan | — | 9,482 |
| Repayment of facility loan principal | (986) | (4,756) |
| Proceeds from issuance of common stock and warrants, net of issuance costs | — | 25,375 |
| Proceeds from issuance of common stock upon exercise of warrants | — | 426 |
| Net cash (used in) provided by financing activities | (986) | 30,527 |
| Net increase (decrease) in cash and cash equivalents | 2,789 | (3,880) |
| Cash and cash equivalents at beginning of period | 7,706 | 11,586 |
| Cash and cash equivalents at end of period | $ 10,495 | $ 7,706 |
| **Supplemental disclosure** | | |
| Cash paid for interest | $ 866 | $ 535 |
| **Supplemental non-cash investing and financing activites** | | |
| Issuance of common stock warrants to lenders | — | 258 |
| Issuance of common stock upon warrant exercises | — | 1,513 |
| Net change in accrued financing costs | 144 | — |

*See accompanying notes.*

## NOTES TO FINANCIAL STATEMENTS

### 1. Organization and Description of Business

CymaBay Therapeutics, Inc. (the "Company" or "CymaBay") is a biopharmaceutical company focused on developing therapies to treat specialty and orphan diseases with high unmet medical need. The Company's two key clinical development candidates are seladelpar (MBX-8025) and arhalofenate. Seladelpar is currently being developed primarily for the treatment of primary biliary cholangitis (PBC). Arhalofenate is being developed for the treatment of gout and has been outliscensed in the United States. The Company was incorporated in Delaware in October 1988 as Transtech Corporation. The Company's headquarters and operations are located in Newark, California and it operates in one segment.

The Company is an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has irrevocably elected not to avail itself of this exemption from new or revised accounting standards, and, therefore, is subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

### Liquidity

The Company has incurred net operating losses and negative cash flows from operations since its inception. During the year ended December 31, 2016, the Company incurred a net loss of $26.7 million and used $23.4 million of cash in operations. At December 31, 2016, the Company had an accumulated deficit of $423.0 million. CymaBay expects to incur substantial research and development expenses as it continues to study its product candidates in clinical trials. To date, none of the Company's product candidates have been approved for marketing and sale, and the Company has not recorded any revenue from product sales. As a result, management expects operating losses to continue in future years. The Company's ability to achieve profitability is dependent primarily on its ability to successfully develop, acquire or in-license additional product candidates, continue clinical trials for product candidates currently in clinical development, obtain regulatory approvals, and support commercialization activities for partnered product candidates. Products developed by the Company will require approval of the U.S. Food and Drug Administration (FDA) or a foreign regulatory authority prior to commercial sale. The regulatory approval process is expensive, time-consuming, and uncertain, and any denial or delay of approval could have a material adverse effect on the Company. Even if approved, the Company's products may not achieve market acceptance and will face competition from both generic and branded pharmaceutical products.

As of December 31, 2016, the Company's cash, cash equivalents and marketable securities totaled $17.0 million. These funds, together with $9.4 million received from financings and $5.0 million received from a license arrangement in January and February 2017, are expected to satisfy the Company's liquidity requirements through at least the next 12 months. The Company expects to incur substantial expenditures in the future for the development and potential commercialization of its product candidates. Because of this, the Company expects its future liquidity and capital resource needs will be impacted by numerous factors, including but not limited to, the repayment of the Company's facility loan, the timing of initiation of planned clinical trials, including phase 2 trials to study the therapeutic benefits of seladelpar on patients with certain orphan diseases. The Company has and expects to obtain additional funding to develop its products and fund future operating losses through equity offerings, debt financing, one or more possible licenses, collaborations or other similar arrangements with respect to development and/or commercialization rights of its product candidates, or a combination of the above. It is unclear if or when any such transactions will occur, on satisfactory terms or at all. The Company's failure to raise capital as and when needed could have a negative impact on its financial condition and its ability to pursue its business strategies. If adequate funds are not available, the Company may be required to reduce current development activities or limit or cease operations.

**2. Summary of Significant Accounting Policies**

**Basis of Presentation and Use of Estimates**

The accompanying 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 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 reporting period and updated to reflect current information and any changes in estimates will generally be reflected in the period first identified.

**Reclassifications**

Accrued interest receivable as of December 31, 2015 which was previously presented separately has been combined with other current assets in the accompanying balance sheets to conform to the December 31, 2016 presentation. Additionally, the Company has reclassified retainer fees paid to a vendor from prepaid expenses to other assets in the accompanying balance sheet as of December 31, 2015 to conform to the December 31, 2016 presentation.

**Fair Value of Financial Instruments**

The Company's financial instruments during the periods reported consist of cash and cash equivalents, marketable securities, prepaid expenses, other current assets, accounts payable, accrued interest payable, accrued expenses, the Facility Loan, and warrant liabilities. Fair value estimates of these instruments are made at a specific point in time, based on relevant market information. These estimates may be subjective in nature and involve uncertainties and matters of significant judgment. The carrying amounts of financial instruments such as cash and cash equivalents, prepaid expenses, other current assets, accounts payable, accrued expenses, and accrued interest payable approximate the related fair values due to the short maturities of these instruments. Based on prevailing borrowing rates available to the Company for loans with similar terms, the Company believes the fair value of the Facility Loan, considering level 2 inputs, approximates its carrying value.

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

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

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

Level 3—Inputs that are significant to the fair value measurement and are unobservable (i.e. supported by little market activity), which requires the reporting entity to develop its own valuation techniques and assumptions.

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

| (In thousands) | As of December 31, 2016 | | | |
|---|---|---|---|---|
| **Description** | **Level 1** | **Level 2** | **Level 3** | **Fair Value** |
| Cash equivalents: | | | | |
| Money market funds | $9,456 | $ — | $ — | $ 9,456 |
| Commercial paper | — | 599 | — | 599 |
| Corporate debt securities | — | 500 | — | 500 |
| Total cash equivalents | 9,456 | 1,099 | — | 10,555 |
| Short-term investments: | | | | |
| Commercial paper | — | 4,295 | — | 4,295 |
| Corporate debt securities | — | 2,204 | — | 2,204 |
| Total short-term investments | — | 6,499 | — | 6,499 |
| Total assets measured at fair value | $9,456 | $ 7,598 | $ — | $ 17,054 |
| Warrant liability | $ — | $ — | $1,145 | $ 1,145 |
| Total liabilities measured at fair value | $ — | $ — | $1,145 | $ 1,145 |

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

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

There were no transfers between Level 1 and Level 2 during the periods presented.

As of December 31, 2016 and 2015, financial instruments measured using Level 3 inputs consisted of the Company's warrants which are accounted for as liabilities. The warrants are valued using a binomial lattice option-pricing model, the significant inputs for which include exercise price of the warrants, market price of the underlying common shares, expected term, expected volatility, the risk-free rate, key strategic initiatives,

probability of success related to those initiatives, and the expected changes in stock price that follow announcements of the Company's strategic initiatives. 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.

The following tables set forth a summary of the changes in the fair value of our liabilities measured using Level 3 inputs (in thousands):

| | For the Twelve Months Ended December | |
|---|---|---|
| | 2016 | 2015 |
| Balance, beginning of period | $ 1,220 | $ 13,596 |
| Issuance of financial instrument | — | 258 |
| Change in fair value | (75) | (11,121) |
| Settlement of financial instrument | — | (1,513) |
| Balance, end of period | $ 1,145 | $ 1,220 |

**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, commercial paper, and asset-backed securities and are classified as "available-for-sale." Management may liquidate any of these investments in order to meet the Company's liquidity needs in the next year. Accordingly, any investments with contractual maturities greater than one year from the balance sheet date are classified as short-term in the accompanying balance sheets.

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

**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, 2016 and 2015, cash restricted under these arrangements was $170,000. 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. We are exposed to credit risk in the event of a default by the financial institutions holding our cash, cash equivalents and investments and issuers of investments to the extent recorded on the balance sheets.

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

**Property and Equipment**

Property and equipment is recorded 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, 2016.

**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 as deferred rent in the accompanying balance sheets.

**Revenue Recognition**

The Company recognizes revenue when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or services have been rendered, (iii) the price is fixed or determinable, and (iv) collectability is reasonably assured. Payments received in advance of work performed are recorded as deferred revenue and recognized when earned.

Collaboration and license agreements may include non-refundable upfront license fees, contingent consideration payments based on the achievement of defined collaboration objectives and royalties on sales of commercialized products. The Company's performance obligations under collaboration and license agreements may include the license or transfer of intellectual property rights, obligations to provide research and development services and related materials and obligations to participate on certain development and/or commercialization committees with the collaborators.

If the Company determines that multiple deliverables in an arrangement exist, the consideration is allocated to one or more units of accounting based upon the relative-selling-price of each element in an arrangement. The relative-selling-price used for each deliverable is based on vendor-specific objective evidence, if available, third-party evidence

if vendor-specific objective evidence is not available, or estimated selling price if neither vendor-specific or third-party evidence is available. The Company identifies deliverables at the inception of the arrangement. Each deliverable is accounted for as a separate unit of accounting if both of the following criteria are met: (1) the delivered item or items have value to the customer on a standalone basis and (2) for an arrangement that includes a general right of return relative to the delivered items, delivery or performance of the undelivered items is considered probable and substantially in the Company's control. Non-refundable upfront payments received and allocated to separate units of accounting are recognized as revenue when the four basic revenue recognition criteria are met for each unit of accounting.

The Company recognizes payments that are contingent upon achievement of a substantive milestone in their entirety in the period in which the milestone is achieved. Milestones are defined as events that can only be achieved based on the Company's performance and there is substantive uncertainty about whether the event will be achieved at the inception of the arrangement. Events that are contingent only on the passage of time or only on counterparty performance are not considered milestones subject to this guidance. Further, the amounts received must relate solely to prior performance, be reasonable relative to all of the deliverables and payment terms within the agreement and commensurate with the Company's performance to achieve the milestone after commencement of the agreement. Any contingent payment that becomes payable upon achievement of events that are not considered substantive milestones are allocated to the units of accounting previously identified at the inception of an arrangement when the contingent payment is received and revenue is recognized based on the revenue recognition criteria for each unit of accounting.

**Research and Development Expenses**

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

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

**Stock-Based Compensation**

Employee and director stock-based compensation is measured at fair value on the grant date of the award. Compensation cost is recognized as expense on a straight-line basis over the vesting period for options and on an accelerated basis for stock options with performance conditions, net of estimated forfeitures. For stock options with performance conditions, the Company evaluates the probability of achieving performance conditions at each

reporting date. The Company begins to recognize the expense when it is deemed probable that the performance conditions will be met. The Company uses the Black-Scholes option pricing model to determine the fair value of stock option awards. The determination of fair value for stock-based awards using an option-pricing model requires management to make certain assumptions regarding subjective input variables such as expected term, dividends, volatility and forfeiture rates. The Company is also required to make estimates as to the probability of achieving the specific performance criteria. If actual results are not consistent with the Company's assumptions and judgments used in making these estimates, the Company may be required to increase or decrease compensation expense, which could be material to the Company's results of operations.

Equity awards granted to non-employees are valued using the Black-Scholes option pricing model. Stock-based compensation expense for nonemployee services is subject to remeasurement as the underlying equity instruments vest and is recognized as an expense over the period during which services are received.

**Common Stock Warrant Liabilities**

The Company's outstanding common stock warrants issued in connection with certain equity and debt financings that occurred in 2013 through 2015 are classified as liabilities in the accompanying balance sheets because of certain contractual terms that preclude equity classification. The warrants are recorded at fair value using a binomial lattice option-pricing model. The warrants are re-measured at each financial reporting period until the warrants are exercised or expire, with any changes in fair value being recognized as a component of other income (expense), net in the accompanying condensed statements of operations and comprehensive loss.

**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. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date. 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 the Company establishes or reduces the valuation allowance related to the deferred tax assets, the 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 is required to file federal and state income tax returns in the United States. The preparation of these income tax returns requires the Company to interpret the applicable tax laws and regulations in effect which could affect the amount of tax paid to these jurisdictions.

The Company records interest related to income tax reserves, if any, as interest expense, 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 tax reserves during the years ended December 31, 2016 and 2015.

**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 stockholders' equity, and is stated net of related tax effects, if any.

**Net Income (Loss) Per Common Share**

Basic net loss per share of common stock is based on the weighted average number of shares of common stock outstanding equivalents during the period. Diluted net loss per share of common stock is calculated as the weighted average number of shares of common stock outstanding adjusted to include the assumed exercises of stock options and common stock warrants, if dilutive.

The calculation of diluted loss per share also requires that, to the extent the average market price of the underlying shares for the reporting period exceeds the exercise price of the common stock warrants and the presumed exercise of such securities are dilutive to earnings (loss) per share for the period, adjustments to net income or net loss used in the calculation are required to remove the change in fair value of the common stock warrant liability for the period. Likewise, adjustments to the denominator are required to reflect the related dilutive shares.

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

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

| | Year Ended December 31, | |
|---|---|---|
| | **2016** | **2015** |
| Numerator: | | |
| Net loss allocated to common stock—basic | $ (26,671) | $ (15,529) |
| Adjustment for revaluation of warrants | — | (94) |
| Net loss allocated to common stock—diluted | $ (26,671) | $ (15,623) |
| Denominator: | | |
| Weighted average number of common stock shares outstanding—basic | 23,447,003 | 18,900,473 |
| Dilutive common stock warrants | — | 16,740 |
| Weighted average number of common stock shares outstanding—diluted | 23,447,003 | 18,917,213 |
| **Net loss per share—basic** | $ (1.14) | $ (0.82) |
| **Net loss per share—diluted** | $ (1.14) | $ (0.83) |

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, | |
|---|---|---|
| | 2016 | 2015 |
| Common stock warrants | 1,667 | 1,553 |
| Common stock options | 2,394 | 1,804 |
| Performance-based stock options | 327 | — |
| Incentive awards | 239 | 245 |
| | 4,627 | 3,602 |

**Recent Accounting Pronouncements**

***Accounting Standards Update 2014-09***

In May 2014, the FASB issued Accounting Standards Update 2014-09, Revenue from Contracts with Customers and related amendments. Subsequently, the Financial Accounting Standards Board (the FASB) issued the following standards related to ASU 2014-09: ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations; ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing; and ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients. This guidance outlines a new, and single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes nearly all of the existing revenue recognition guidance, including industry-specific guidance. This new revenue recognition model provides a five-step analysis in determining when and how revenue is recognized. The new model will require revenue recognition to depict the transfer of promised goods or services to customers in an amount that reflects the consideration a company expects to receive in exchange for those goods or services.

The new revenue standard permits two methods of adoption: retrospectively to each prior reporting period presented (full retrospective method), or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (the modified retrospective method). The Company plans to adopt the new revenue standard in the first quarter of 2018 using the modified retrospective method.

While the Company has not completed an assessment of the impact of adoption, the adoption of this guidance may have a material effect on the Company's financial statements. At the end of 2016, the Company entered into a license agreement. Before executing this agreement, the Company has had no revenues for the last two years. The consideration the Company is eligible to receive under this agreement includes an upfront payment, milestone payments, and royalties. This license agreement is unique and will need to be assessed separately under the five-step process under the new standard. The Company is currently in the early stages of analyzing this agreement to determine the differences in the accounting treatment under the new revenue standard compared to the current accounting treatment. The new revenue standard differs from the current accounting standard in many respects, such as in the accounting for variable consideration, including milestone payments and royalties.

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

In August 2014, the FASB issued guidance codified in ASC 205, Presentation of Financial Statements — Going Concern. Accounting Standards Update 2014-15 requires an entity's management to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern and if those conditions exist, to make the required disclosures. The ASU aligns the interpretation of substantial doubt with the definition of "probable" pursuant to ASC 450, *Contingencies*, meaning that a company's inability to meet obligations as they come due within one year after the issuance date must be likely to occur. If substantial doubt exists, management is required to disclose their conclusion and must further assess whether their plans will or will not alleviate substantial doubt. The results of this additional assessment determine other specific disclosure requirements. The Company adopted this standard in the fourth quarter of 2016 and the adoption did not have a significant impact on the Company's financial statements.

***Accounting Standards Update 2015-03***

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

***Accounting Standards Update 2016-02***

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The new standard requires the recognition of assets and liabilities arising from lease transactions on the balance sheet and the disclosure of key information about leasing arrangements. Accordingly, a lessee will recognize a lease asset for its right to use the underlying asset and a lease liability for the corresponding lease obligation. Both the asset and liability will initially be measured at the present value of the future minimum lease payments over the lease term. Subsequent measurement, including the presentation of expenses and cash flows, will depend on the classification of the lease as either a finance or an operating lease. Initial costs directly attributable to negotiating and arranging the lease will be included in the asset. Lessees will also be required to provide additional qualitative and quantitative disclosures regarding the amount, timing and uncertainty of cash flows arising from leases. The new standard is effective for fiscal years beginning after December 15, 2018, and interim periods therein. Early adoption is permitted. The Company is currently evaluating the impact this guidance will have on its financial statements.

***Accounting Standards Update 2016-09***

In March 2016, the FASB issued ASU No. 2016-09, Improvements to Employee Share-Based Payment Accounting, which amends ASC Topic 718, Compensation – Stock Compensation. This guidance simplifies the accounting for the taxes related to stock based compensation, requiring excess tax benefits and deficiencies to be recognized as a component of income tax expense rather than equity. This guidance also requires excess tax benefits and deficiencies to be presented as an operating activity on the statement of cash flows and allows an entity to make an accounting policy election to either estimate expected forfeitures or to account for them as they occur. The amendments in this ASU are effective for annual periods beginning after December 15, 2016 and for the interim periods therein. Early adoption is permitted. The Company is currently evaluating the impact this guidance will have on its financial statements.

**3. Marketable Securities**

Marketable available-for-sale securities as of December 31, 2016 and 2015 consist of the following (in thousands):

| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value |
|---|---|---|---|---|
| As of December 31, 2016: | | | | |
| Short-term investments: | | | | |
| Commercial paper | $ 4,295 | $ — | $ — | $ 4,295 |
| Corporate debt securities | 2,205 | — | (1) | 2,204 |
| | $ 6,500 | $ — | $ (1) | $ 6,499 |

| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value |
|---|---|---|---|---|
| As of December 31, 2015: | | | | |
| Short-term investments: | | | | |
| Commercial paper | $ 5,992 | $ — | $ — | $ 5,992 |
| Government debt securities | 1,509 | — | (2) | 1,507 |
| Corporate debt securities | 21,671 | — | (17) | 21,654 |
| Asset-backed securities | 4,623 | — | (2) | 4,621 |
| | $ 33,795 | $ — | $ (21) | $ 33,774 |

As of December 31, 2016 and 2015, the remaining contractual maturities of the Company's commercial paper, corporate debt securities, and government debt securities were between 1-2 years and asset-backed securities had contractual maturities between 2-5 years. Realized gains and losses were immaterial for the years ended December 31, 2016 and 2015. None of these investments have been in a continuous unrealized loss position for more than 12 months as of December 31, 2016 and 2015.

**4. Certain Balance Sheet Items**

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

| | December 31, 2016 | December 31, 2015 |
|---|---|---|
| Office and computer equipment | $ 177 | $ 176 |
| Purchased software | 83 | 46 |
| Furniture and fixtures | 38 | 33 |
| Leasehold improvements | 65 | 66 |
| Total | 363 | 321 |
| Less accumulated depreciation and amortization | (286) | (257) |
| Property and equipment, net | $ 77 | $ 64 |

Accrued liabilities consist of the following (in thousands):

| | December 31, 2016 | December 31, 2015 |
|---|---|---|
| Accrued compensation | $ 1,839 | $ 1,010 |
| Accrued pre-clinical and clinical trial expenses | 1,623 | 2,015 |
| Accrued professional fees | 982 | 283 |
| Other accruals | 57 | 28 |
| Total accrued liabilities | $ 4,501 | $ 3,336 |

**5. Collaboration and License Agreements**

***Kowa Pharmaceuticals America, Inc.***

On December 30, 2016, the Company entered into a license agreement with Kowa Pharmaceuticals America, Inc. ("Kowa"). Pursuant to the license agreement, the Company granted to Kowa an exclusive license, and right to sublicense, certain patent rights and technology related to arhalofenate. Kowa will have exclusive rights to, among other things, develop, use, manufacture, sell and otherwise exploit the licensed technology in the United States (including all possessions and territories). At Kowa's option, the Company may also facilitate the placement of arhalofenate product manufacturing orders under the terms of the Company's existing contract manufacturing agreements. In addition, the Company will complete specified in-process stability testing and non-clinical development services and will participate on a Joint Advisory Committee ("JAC"). Finally, the Company will transfer to Kowa certain arhalofenate product on hand.

Under the license agreement, Kowa agreed to pay the Company a non-refundable up-front payment of $5 million upon contract execution which was subsequently received in mid-January 2017. The Company is also eligible to receive up to $200 million in contingent payments based upon either the initiation or achievement of specified development and sales milestones. Finally, the Company will receive tiered, double digit royalties on any product sales and a percentage of any revenue earned by Kowa from sublicensing.

The Company identified the following three performance deliverables under the license agreement: 1) transfer of intellectual property rights, inclusive of the related technology know-how conveyance and contract manufacturing rights and privileges ("license and know-how"), 2) the obligation to perform specific ongoing research and non-clinical development services, and 3) the delivery of arhalofenate product on hand. The Company's participation on the JAC was not determined to be a deliverable because of the Company's ability to elect to terminate its participation. The Company concluded that the license, the know-how and contract manufacturing rights and privileges together represent a single deliverable, and therefore together should be accounted for as a single unit of accounting. The research and development services and delivery of arhalofenate product each also represent separate deliverables, and therefore each should be accounted for as separate units of accounting. There was no separate consideration identified in the agreement for the deliverables and there was no right of return under the agreement.

The Company considered the provisions of the multiple-element arrangement guidance in determining whether the deliverables outlined above have standalone value. The transfer of license and know-how has standalone value separate from the research and development services and delivery of arhalofenate product, as the agreement allows Kowa to sublicense its rights to the acquired license to a third party. Further, the Company believes that Kowa has research and development expertise with compounds similar to those licensed under the agreement, and the Company has also granted Kowa the rights to either order arhalofenate product from the Company's existing contract manufacturers, or to enter into arrangements with other third parties to develop and manufacture arhalofenate product, thereby allowing Kowa to realize the value of the license and know-how. The license and know-how revenue will be recognized upon the substantial completion of the transfer of know-how. The research and development services will be recognized as revenue over the estimated period services are delivered. The arhalofenate product will be recognized as revenue upon delivery.

As of December 31, 2016, no revenue had been recognized as the up-front payment had not yet been received and delivery had not yet occurred for the license and know-how, research and development services, or the arhalofenate product on hand.

The Company determined the future contingent payments related to the development activities do not meet the definition of a milestone. Under current revenue recognition rules, these amounts will be allocated to the Kowa arrangements' three identified units of accounting when received and recognized as revenue based on the revenue recognition policy for those respective units of accounting. The future contingent payments related to the U.S. sales milestones are recognized upon achievement of the specific milestones. As of December 31, 2016, none of these contingent amounts had been received or recognized as revenue.

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

In June 2006, the Company entered into an exclusive worldwide, royalty-bearing license to seladelpar and certain other PPARd compounds (the "PPARd Products") with Janssen Pharmaceutical NV (Janssen NV), with the right to grant sublicenses to third parties to make, use and sell such PPARd Products. Under the terms of the agreement, the Company has full control and responsibility over the research, development and registration of any PPARd Products and is required to use diligent efforts to conduct all such activities. Janssen NV has the sole responsibility for the preparation, filing, prosecution, maintenance of, and defense of the patents with respect to, the PPARd Products. Janssen NV has a right of first negotiation under the agreement to license a particular PPARd Product from the Company in the event that the Company elects to seek a third party corporate partner for the research, development, promotion, and/or commercialization of such PPARd Products. Under the terms of the agreement Janssen NV is entitled to receive up to an 8% royalty on net sales of PPARd Products.

In June 2010, the Company entered into two development and license agreements with Janssen Pharmaceuticals, Inc. (Janssen), a subsidiary of Johnson and Johnson, to further develop and discover undisclosed metabolic disease target agonists for the treatment of T2DM and other disorders and received a one-time nonrefundable technology access fee related to the agreements. The Company received a termination notice

from Janssen, effectively ending these development and licensing agreements in early April 2015. In December 2015, the Company exercised an option pursuant to the terms of one of the original agreements to continue work to research, develop and commercialize compounds with activity against an undisclosed metabolic disease target. Janssen granted the Company an exclusive, worldwide license (with rights to sublicense) under the Janssen know-how and patents to research, develop, make, have made, use, offer for sale and sell such compounds. The Company has full control and responsibility over the research, development and registration of any products developed and/or discovered from the metabolic disease target and is required to use diligent efforts to conduct all such activities.

***DiaTex, Inc.***

In June 1998, the Company entered into a license agreement with DiaTex, Inc. (DiaTex) relating to products containing halofenate, its enantiomers, derivatives, and analogs (the licensed products). The license agreement provides that DiaTex and the Company are joint owners of all of the patents and patent applications covering the licensed products and methods of producing or using such compounds, as well as certain other know-how (the covered IP). As part of the license agreement, the Company received an exclusive worldwide license, including as to DiaTex, to use the covered IP to develop and commercialize the licensed products. The Company also retained the right to sub-license the covered IP. The license agreement contains a $2,000 per month license fee as well as a requirement to make additional payments for development achievements and royalty payments on any sales of licensed products. DiaTex is entitled to up to $0.8 million for the future development of arhalofenate, as well as royalty payments on commercial sales of products containing arhalofenate. No development payments were made or due as of and for the years ended December 31, 2016 and 2015 and no royalties have been paid to date. In December 2016, the agreement was amended by the parties to change the timing of a specified development milestone.

**6. Facility Loans**

**2013 Term Loan Facility**

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

At the time the first $5 million tranche of the facility loan was drawn down, the Company issued warrants exercisable for a total of 121,739 shares of the Company's common stock to the lenders at an exercise price of $5.00 per share. Upon issuance, the fair value of a warrant liability was recorded and is being revalued at each balance sheet date until the warrants are exercised or expire.

**2015 Term Loan Facility**

On August 7, 2015, the Company entered into a Loan and Security Agreement pursuant to which it refinanced its existing 2013 Term Loan Facility with Oxford Finance LLC and Silicon Valley Bank, for an aggregate amount of up to $15 million, referred to here as the 2015 Term Loan Facility. The first $10 million tranche of this new loan facility was made available to the Company immediately upon the closing and was used in part to retire all $4.1 million of the Company's existing debt outstanding under the 2013 Term Loan Facility, and to settle accrued interest and closing costs with the lenders. The remaining $5 million, referred to as the

second tranche, was made available to the Company until March 31, 2016, for draw down upon the announcement of a qualified out-license or co-development arrangement for arhalofenate, the Company's gout therapy drug candidate, which includes an upfront payment of not less than $35.0 million (the "second draw milestone"). Because the present value of the future cash flows under the modified loan terms did not exceed the present value of the future cash flows under the previous loan terms by more than 10%, the Company treated this refinancing as a modification. The remaining debt discount costs will be amortized over the remaining term of the Loan and Security Agreement using the effective interest rate method. The $5.0 million second tranche expired unused in March 2016 as the second draw milestone was not achieved.

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

At the closing, the Company also agreed to pay a facility fee of 1.00% of the 2015 Term Loan Facility commitment. In addition, the Company issued warrants exercisable for a total of 114,436 shares of its common stock to the lenders at an exercise price of $2.84 per share, and with a term of ten years. Upon issuance, the fair value of a warrant liability of $0.3 million was recorded in the accompanying balance sheet and is being revalued at each balance sheet date until the warrants are exercised or expire.

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

The 2015 Term Loan Facility contains customary representations and warranties and customary affirmative and negative covenants applicable to the Company, and also includes defined customary events of default which include but are not limited to a material adverse change in the Company's business, operations or condition (financial or otherwise), a material impairment of the prospect of repayment of any portion of the term loan, or a material impairment in the perfection or priority of the collateral agent's lien in the collateral or in the value of such collateral. As of December 31, 2016, the Company was in compliance with the term loan covenants and there were no events of default.

The term loan facility, debt discounts and final payment balances as of December 31, 2016 and 2015 are as follows (in thousands):

| | December 31, | |
|---|---|---|
| | 2016 | 2015 |
| Principal payments due under the loan facility | $9,014 | $10,000 |
| Less: unamortized debt discount | (599) | (929) |
| Plus: accreted value of final payment | 383 | 237 |
| Term loan facility, net | $8,798 | $ 9,308 |

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

| | Principal Payments |
|---|---|
| Year ending December 31: | |
| 2017 | 3,137 |
| 2018 | 3,423 |
| 2019 | 2,454 |
| Total future principal payments due under loan agreement | $ 9,014 |

### 7. Commitments and Contingencies

**Operating Lease Commitments**

Rent expense was $0.3 million for each of the years ended December 31, 2016 and 2015. The Company leases 8,894 square feet of office space in Newark, California pursuant to a lease which commenced January 16, 2014 and expires on December 31, 2018.

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

| | Lease Payments |
|---|---|
| Year ending December 31: | |
| 2017 | 222 |
| 2018 | 228 |
| Total future minimum payments | $ 450 |

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

### 8. Stockholders' Equity

The Company is authorized to issue 10,000,000 shares of preferred stock as of December 31, 2016 and 2015, respectively. The Company is authorized to issue 100,000,000 shares of common stock as of December 31, 2016 and 2015, respectively.

**Common Stock Issuances**

On July 25, 2014, the Company completed a public offering of 4.6 million 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, the Company filed a $100 million registration statement on Form S-3 with the SEC and also entered into an at-the-market facility (ATM) to sell up to $25 million of common stock under the registration statement, under which, as of December 31, 2015, the Company has sold shares of common stock with aggregate net proceeds of $4.3 million.

On July 27, 2015, pursuant to a shelf registration statement on Form S-3, the Company completed the issuance of 8.2 million shares of its common stock at $2.81 per share in an underwritten public offering, which the Company refers to as the 2015 public offering. Net proceeds to the Company in connection with this offering were approximately $21.1 million after deducting underwriting discounts, commissions and other offering expenses.

**Common Stock Warrants**

In connection with a 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 the Company's common stock at an exercise price of $5.75 per share (referred to as the 2013 financing warrants). The Company also issued seven-year warrants to purchase 121,739 shares of the Company's common stock to certain lenders at an exercise price of $5.00 per share in September 2013 and in connection with the 2015 loan facility, the Company issued ten-year warrants to purchase 114,436 shares of its common stock to its lenders at an exercise price of $2.84 per share (referred to as the lender warrants).

The 2013 financing warrants contain anti-dilution provisions that are contingent on the occurrence of a major transaction (e.g. merger, reorganization, business combination, change in control or a similar transaction, liquidation or bankruptcy) which precludes them from being indexed to the Company's common stock. Such provisions could also result in the settlement of the 2013 financing warrants for more shares of common stock than the Company has authorized. Due to these provisions, the Company is required to account for the 2013 financing warrants and the lender warrants as liabilities 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 revalued and 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, 2016 and 2015 using a binomial lattice option pricing model. The resulting decreases in fair value of $0.1 million for the year ended December 31, 2016 and $11.1 million for the year ended December 31, 2015 were recorded as revaluation gains in other income (expense), net in the Company's statement of operations and comprehensive loss.

**Shares of Common Stock Authorized for Issuance**

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

| | December 31, 2016 | December 31, 2015 |
|---|---|---|
| Common stock warrants | 1,667,398 | 1,667,398 |
| Equity incentive plans | 3,456,253 | 2,284,421 |
| Total reserved shares of common stock | 5,123,651 | 3,951,819 |

### 9. 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 incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards, performance cash awards and other stock awards by the Company. These awards may be granted to employees, members of the Board of Directors, and consultants. 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 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.

**Stock Plan Activity**

As of December 31, 2016, there were 496,120 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 1,172,350 shares on January 1, 2017.

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, 2014 | 991,010 | $ 6.09 | 8.91 | $ 4,559 |
| Options granted | 845,703 | 9.00 | | |
| Options exercised | — | 0 | | |
| Options forfeited | (15,631) | 4.75 | | |
| Options expired | (16,999) | 12.31 | | |
| Outstanding as of December 31, 2015 | 1,804,083 | 7.41 | 8.24 | $ — |
| Options granted | 646,667 | 1.28 | | |
| Options exercised | — | 0 | | |
| Options forfeited | (14,319) | 4.50 | | |
| Options expired | (42,043) | 25.01 | | |
| Outstanding as of December 31, 2016 | 2,394,388 | $ 5.46 | 7.75 | $ 349 |
| Vested and expected to vest as of December 31, 2016 | 2,351,745 | $ 5.50 | 7.73 | $ 331 |
| Exercisable as of December 31, 2016 | 1,310,883 | $ 6.15 | 7.18 | $ 3 |

**Vested and Unvested Awards**

The total fair value of options including performance options vested was $2.2 million for each of the years ended December 31, 2016 and 2015.

As of December 31, 2016, and 2015 the total compensation expense related to unvested employee stock options including performance options to be recognized in future periods, excluding estimated forfeitures, was $3.5 million and $4.8 million, respectively. The weighted-average periods over which this compensation expense is expected to be recognized are 1.8 years and 2.6 years as of December 31, 2016 and 2015, respectively.

**Performance Options**

In July 2016, the Company granted 327,000 performance-based stock options (PSOs) to executives and senior officers. PSOs represent a contingent right to purchase the Company's common stock upon the achievement of specific conditions. Specifically, these PSOs vest upon the achievement of certain clinical development and capital raising milestones which must occur before December 31, 2016. In December 2016, the PSOs were modified by extending the term by one month to January 31, 2017.

The following table summarizes performance option activity:

| | Shares Subject to Outstanding Options | Weighted-Average Exercise Price of Options |
|---|---|---|
| Outstanding as of December 31, 2015 | — | $ — |
| Options granted | 327,000 | 1.82 |
| Outstanding as of December 31, 2016 | 327,000 | $ 1.82 |

In 2016, the clinical development milestone was achieved and the related expense of $199,000 was recognized. The modification to extend the term of the PSOs did not have a material impact on the Company's financial statements. The unrecognized stock-based compensation related to the remaining PSOs was $192,000 as of December 31, 2016, and its recognition is dependent upon the achievement of the capital raising milestone. Subsequent to December 31, 2016, the capital raising milestone was achieved within the modified term. Accordingly, all stock-based compensation expense related to this milestone will be recorded in 2017.

**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 have a term of 10 years and were initially scheduled to vest 100% on the second anniversary of their grant date. 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 Company is recognizing the value of the incentive awards over the remaining four year vesting period.

The Company recorded $272,000 and $323,000 of stock based compensation expense in the years ended December 31, 2016 and 2015, respectively, pertaining to its incentive awards.

**Options Granted to Nonemployees**

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 18,000 and 10,000 shares of common stock, in 2016 and 2015, respectively. As of December 31, 2016, options to purchase 28,410 shares of common stock remained unvested, and compensation related to these stock options is subject to remeasurement each reporting period as the shares vest. In 2013, the Company also issued an incentive award for 2,335 shares to a scientific advisor, of which 584 shares remained unvested as of December 31, 2016. The Company recorded $17,510 and $21,265 of expense in the years ended December 31, 2016 and 2015, respectively, related to these options and awards.

**Stock-Based Compensation Expense**

Stock-based compensation expense, net of estimated forfeitures, included in the statements of operations and comprehensive loss is as follows (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2016 | 2015 |
| Research and development | $ 995 | $ 844 |
| General and administrative | 1,478 | 1,643 |
| Total stock-based compensation expense | $2,473 | $2,487 |

**Valuation Assumptions**

The following table presents the weighted-average assumptions the Company used in the Black-Scholes option-pricing model to derive the grant date fair values of stock options and performance-based stock options along with the resulting estimated weighted-average grant date fair values per share:

| | Year Ended December 31, | |
|---|---|---|
| | 2016 | 2015 |
| Expected term | | |
| Options | 6.1 yrs | 6.1 yrs |
| Performance options | 5.1 yrs | — |
| Expected volatility | | |
| Options | 80% | 78% |
| Performance options | 85% | — |
| Risk-free interest rate | | |
| Options | 1.57% | 1.65% |
| Performance options | 1.56% | — |
| Expected dividend yield | | |
| Options | — | — |
| Performance options | — | — |
| Weighted-average grant date fair value per share | | |
| Options | $ 0.89 | $ 6.13 |
| Performance options | $ 1.20 | — |

*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, 2016 and 2015, 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. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

*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.

*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 significant for the years ended December 31, 2016 and 2015.

**10. 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, 2016 and 2015.

**11. Income Taxes**

No provision for U.S. income taxes exists due to tax losses incurred in all periods presented. All losses incurred were U.S. based. Significant components of the Company's deferred tax assets are as follows (in thousands):

| | December 31 | |
|---|---|---|
| | 2016 | 2015 |
| Deferred tax assets: | | |
| Federal and state net operating loss carryforwards | $ 88,111 | $ 79,966 |
| Capitalized research and development | 22,272 | 22,287 |
| Federal and state tax credit carryforwards | 8,141 | 7,571 |
| Stock based compensation | 2,080 | 1,384 |
| Other | 974 | 628 |
| Total deferred tax assets | 121,578 | 111,836 |
| Valuation allowance | (121,578) | (111,836) |
| 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 $9.7 million during the year ended December 31, 2016 and increased $9.8 million during the year ended December 31, 2015.

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

| | December 31 | |
|---|---|---|
| | 2016 | 2015 |
| Expected income tax benefit at federal statutory tax rate | $(9,068) | $(5,280) |
| Change in valuation allowance | 9,775 | 9,815 |
| State income taxes, net of federal benefit | (458) | (618) |
| Permanent items | 196 | (3,542) |
| Research credits | (445) | (375) |
| 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, 2016 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 2008-2016, 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, 2016, the Company has federal net operating loss carryforwards of $229.1 million and state net operating loss carryforwards of $175.1 million to offset future taxable income, if any. In addition, the Company has federal research and development tax credit carry forwards of $7.7 million and state research and

development tax credit carryforwards of $6.3 million. If not utilized, the federal net operating loss and tax credit carryforwards will expire beginning in 2024 through 2036 and the state net operating loss carryforwards will expire beginning in 2017 through 2036. 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 |
|---|---|
| Balances as of December 31, 2014 | $1,991 |
| Increases related to prior year tax positions | — |
| Increases related to 2015 tax positions | 136 |
| Balances as of December 31, 2015 | $2,127 |
| Increases related to prior year tax positions | — |
| Increases related to 2016 tax positions | 159 |
| Balances as of December 31, 2016 | $2,286 |

The unrecognized tax benefits, if recognized, would not have an impact on the Company's effective tax rate assuming the Company continues to maintain a full valuation allowance position. Based on prior year's operations and experience, 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 unexpected or unusual items 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 2016 remain open to examination by the major taxing authorities.

**12. 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 in each of the years ended December 31, 2016 and 2015 in monthly cash retainers.

**13. Subsequent Events**

On January 1, 2017, the share reserve of the Company's 2013 Equity Incentive Plan, or 2013 Plan, automatically increased by 1,172,350 shares. In addition, the Company granted to employees and consultants stock options to purchase 1,016,301 shares of common stock in January 2017.

During January 2017, the Company utilized its ATM facility to offer and sell 124,100 shares of common stock for net proceeds of $158,000 as permitted under the Company's shelf registration statement on Form S-3 and its related prospectus supplements.

On February 2, 2017, pursuant to the Company's shelf registration statement on Form S-3, the Company completed the issuance of 5.2 million shares of common stock at $1.93 per share which the Company refers to as the 2017 public offering. Net proceeds to the Company in connection with the 2017 public offering were approximately $9.2 million after deducting underwriting discounts, commissions and other offering expenses.

**Item 15. Form 10-K Summary**

None.

## 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, 2017
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<br>Harold Van Wart | Chief Executive Officer and Director<br>*(Principal Executive Officer)* | March 23, 2017 |
| /s/ Sujal Shah<br>Sujal Shah | Chief Financial Officer<br>*(Principal Financial and Accounting Officer)* | March 23, 2017 |
| /s/ Robert J. Wills<br>Robert J. Wills, Ph.D. | Director | March 23, 2017 |
| /s/ Carl Goldfischer<br>Carl Goldfischer, M.D. | Director | March 23, 2017 |
| /s/ Robert Booth<br>Robert Booth, Ph.D. | Director | March 23, 2017 |
| /s/ Kurt von Emster<br>Kurt von Emster, CFA | Director | March 23, 2017 |

| Name and Signature | Title | Date |
|---|---|---|
| /s/ Caroline Loewy<br>Caroline Loewy | Director | March 23, 2017 |
| /s/ Evan A. Stein<br>Evan A. Stein, M.D., Ph D. | Director | March 23, 2017 |
| /s/ Paul F. Truex<br>Paul F. Truex | Director | March 23, 2017 |
| /s/ Robert J. Weiland<br>Robert J. Weiland | Director | March 23, 2017 |

## 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# | 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.) |
| 10.6# | 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.) |
| 10.7# | 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.) |
| 10.8# | 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.) |
| 10.9# | 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.) |
| 10.10* | 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.) |

| Exhibit No. | Description of Document |
|---|---|
| 10.11* | 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.) |
| 10.12* | 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.) |
| 10.13 | 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.) |
| 10.14* | 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.) |
| 10.15* | 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.) |
| 10.16* | 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.) |
| 10.17* | 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.) |
| 10.18# | 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.) |
| 10.19* | Non-Employee Director Compensation Program |
| 10.20# | PPARd License Agreement, dated June 20, 2006, by and between Metabolex, Inc. and Janssen Pharmaceutical 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.) |
| 10.21# | Master Services Agreement, dated September 2, 2015, between CymaBay Therapeutics, Inc. and Pharmaceutical Research Associates, Inc. (Filed with the SEC as Exhibit 10.1 to our Form 10-Q, filed with the SEC on November 12, 2015, SEC File No. 001-36500.) |
| 10.22 | Loan and Security Agreement, dated August 7, 2015, by and among CymaBay Therapeutics, Inc., Oxford Finance LLC, and Silicon Valley Bank (Filed with the SEC as Exhibit 10.2 to our Form 10-Q, filed with the SEC on November 12, 2015, SEC File No. 001-36500.) |
| 10.23* | Amendment to Offer Letter, dated February 23, 2016, between Cymabay Therapeutics, Inc. and Kirk Rosemark. (Filed with the SEC as Exhibit 10.23 to our Form 10-K, filed with the SEC on March 29, 2016, SEC File No 001-36500). |
| 10.24* | Amendment to Offer Letter, dated January 27, 2016, between Cymabay Therapeutics, Inc. and Robert Martin. (Filed with the SEC as Exhibit 10.24 to our Form 10-K, filed with the SEC on March 29, 2016, SEC File No 001-36500). |
| 10.25* | Amendment to Offer Letter, dated February 23, 2016, between Cymabay Therapeutics, Inc. and Patrick O'Mara. (Filed with the SEC as Exhibit 10.25 to our Form 10-K, filed with the SEC on March 29, 2016, SEC File No 001-36500). |

| Exhibit No. | Description of Document |
|---|---|
| 10.26* | Compensation Arrangements with certain Executive Officers (Filed with the SEC under Item 5.02 of our Form 8-K, filed with the SEC on January 29, 2016, and January 24, 2017, SEC File No 001-36500). |
| 10.27## | Exclusive License Agreement, between CymaBay Therapeutics, Inc. and Kowa Pharmaceuticals America, Inc., dated December 30, 2016. |
| 10.28## | Second Amendment to License and Development Agreement between CymaBay Therapeutics, Inc. and DiaTex, Inc., dated December 23, 2016 |
| 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 |
| 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 grant of confidential treatment, which portions were omitted and filed separately with the Securities and Exchange Commission.

## 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.

**CymaBay Therapeutics, Inc.**

**Amended and Restated**
**Non-Employee Directors Compensation Program**

In January 2017, 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 having completed a minimum of twelve months of service will receive an additional equity award of an option to purchase 15,000 shares of our common stock. In the event the non-employee director has served less than twelve months, an equity award of an option to purchase up to a maximum of 15,000 shares of our common stock may be awarded at the discretion of the Board or Compensation Committee. If a new board member joins our board of directors, the director will receive an initial stock option to purchase 30,000 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 10.27**

**[ * ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

# Exclusive License Agreement

between

**CymaBay Therapeutics, Inc.**
**(as the licensor)**

and

**Kowa Pharmaceuticals America, Inc.**
**(as the licensee)**

dated as of

December 30, 2016

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

# EXCLUSIVE LICENSE AGREEMENT

This Exclusive License Agreement (this "***Agreement***") dated as of this 30th day of December, 2016 (the "***Effective Date***"), is between CymaBay Therapeutics, Inc., a Delaware corporation having offices located at 7999 Gateway Blvd., Suite 130, Newark, California, U.S.A. ("***CymaBay***"), and Kowa Pharmaceuticals America, Inc., a Delaware corporation having offices located at 530 Industrial Park Blvd., Montgomery, Alabama, U.S.A. ("***Kowa***"). Each of CymaBay and Kowa may be referred to hereinafter individually as a "***Party***" and together as the "***Parties***."

## Recitals

A. CymaBay (f/k/a Metabolex, Inc.) is a party to that certain License and Development Agreement dated June 30, 1998 between Metabolex, Inc., as licensee, and DiaTex, Inc. ("***DiaTex***"), as licensor, as amended by that certain First Amendment dated April 15, 1999 (the "***DiaTex License Agreement***").

B. Kowa wishes to obtain from CymaBay, and CymaBay wishes to grant to Kowa, an exclusive sublicense under the rights granted to CymaBay under the DiaTex License Agreement as well as a license to all of CymaBay's other rights relating the Licensed Product in the Territory for Development and Commercialization of the Licensed Product in the Territory in the Field (each as defined below).

## Agreement

The Parties agree as follows:

## ARTICLE 1

## DEFINITIONS

Capitalized terms, when used in this Agreement, will have the meanings ascribed to them or referenced on **Schedule 1**.

## ARTICLE 2

## DEVELOPMENT, MANUFACTURING, REGULATORY

### 2.1 Disclosures of Technology to Kowa.

2.1.1 Within [ * ] days after the Effective Date, CymaBay will disclose to Kowa all Licensed Technology described or listed on **Schedule 2** or that is necessary for or was otherwise used by CymaBay in conducting Development of Licensed Product for the Indications, and all information regarding the Licensed Patents that is in CymaBay's Control (including, as soon as reasonably practicable, their complete internal file histories, but provided that if any information therein is subject to attorney-client privilege, the Parties shall discuss in good faith whether, or under what circumstances, such privileged information shall be disclosed), in each case that exists as of the Effective Date and that was not previously disclosed to Kowa, and will provide to Kowa copies of any related documentation in CymaBay's Control that contain any such information.



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

2.1.2 In addition, when available or at any time upon the reasonable request of Kowa, CymaBay will promptly disclose to Kowa any additional Licensed Technology of which CymaBay or Kowa becomes aware, and CymaBay Improvement Technology and information regarding CymaBay Improvement Patents, in each case to the extent existing and not previously disclosed.

2.1.3 Unless otherwise specified on **Schedule 2** or mutually agreed in writing by CymaBay and Kowa, all of the foregoing that constitutes information or Data will be disclosed to Kowa electronically in .PDF format, and at Kowa's request if needed by Kowa and reasonably available to CymaBay (without the need to convert or conduct extensive searches), in the native file format in which it is stored and used by CymaBay and its Affiliates.

**2.2 Development and Manufacturing.**

2.2.1 Kowa, at its own cost and expense, (a) will use Commercially Reasonable Efforts to conduct the Development of the Licensed Product in the Territory set forth on **Schedule 3** (the "***Specified Studies***") and any related activities regarding submissions to Regulatory Authorities, and (b) use Commercially Reasonable Efforts to conduct any other studies which Kowa reasonably determines are necessary to obtain Regulatory Approval for at least one Indication; provided, however, that, (i) if any studies other than the Specified Studies are required to obtain Regulatory Approval of Licensed Product in the Territory for either Indication, Kowa may instead terminate this Agreement pursuant to Section 8.2.3, (ii) in the event that Kowa reasonably determines that any of the Specified Studies is unsuccessful, Kowa will have the right to discontinue or not to commence all remaining Specified Studies and all related activities regarding submissions to Regulatory Authorities by terminating this Agreement pursuant to Section 8.2.3 and (iii) in the event Kowa breaches its obligations in Section 2.2.1(b) CymaBay will not be entitled to any damages or equitable relief and CymaBay's sole right with respect to such breach by Kowa of Section 2.2.1(b) will be to terminate this Agreement pursuant to Section 8.2.5. CymaBay will be responsible, [ * ], for the completion of its ongoing Development activities for the Licensed Product set forth on **Schedule 4** initiated prior to the Effective Date for the Territory. CymaBay's obligations with respect to the Development of the Licensed Product pursuant to this Section 2.2.1 excludes the initiation of any new development studies or activities.

2.2.2 Kowa shall keep CymaBay reasonably informed of the progress and results of all Development activities on the Licensed Product conducted by Kowa and its Affiliates and Sublicensees, including by providing CymaBay timely access to electronic copies of the Kowa Regulatory Data [ * ] promptly after it is available and a disclosure identifying and detailing any Kowa Improvement Technology, promptly after being made or developed. CymaBay and any of its licensee(s) outside the Territory who have executed an agreement with CymaBay with confidentiality provisions preventing disclosure to Third Parties of such Kowa Regulatory Data that are at least as strict as the provisions contained in this Agreement shall have the right to review such disclosed Kowa Regulatory Data in connection with preparing for and conducting Development of the Licensed Product outside the Territory. CymaBay may disclose such Kowa Regulatory Data in confidence to potential licensees of the Licensed Product outside the Territory (solely in connection with a due diligence review and evaluation) who have executed an agreement with CymaBay with confidentiality provisions preventing disclosure to Third Parties of such Kowa Regulatory Data that are at least as strict as the provisions contained in this Agreement. CymaBay shall not, until after approval of an NDA for the Licensed Product is obtained in the Territory, (i) [ * ], (ii) [ * ] or (iii) [ * ]. Kowa shall provide CymaBay with regular reporting (at the JAC meetings) regarding such progress and results of, and plans for, Development.

2.2.3 CymaBay will allow, and will cause CymaBay's contract manufacturing organizations ("***CMOs***") involved in the Development of the Licensed Product in the Territory to allow, Kowa's Representatives, upon reasonable notice and during normal working hours, to inspect the manufacturing sites, manufacturing records and samples of the Licensed Product held or controlled by CymaBay or the CMOs. In connection with Kowa's Development of the Licensed Product pursuant to Section 2.2.1, CymaBay will promptly (and in no event later than [ * ] days after the Effective Date) (i) instruct in writing [ * ] that each such party is authorized to provide directly to Kowa (solely for Kowa's use in connection with its exercise of its rights under this Agreement), the following documents and information generated on CymaBay's behalf under such agreements: all available documents and information relating to the manufacturing processes for Licensed Product and related analytical test procedures, and all results of analytical (including stability) testing on Licensed Products, (ii) use Commercially Reasonable Efforts to [ * ], (iii) assist Kowa (if requested by Kowa) in Kowa's efforts to [ * ] under which Kowa will have the right (x) to [ * ] and (y) to [ * ], (iv) provide waivers of any provisions requiring the Licensed Product to be exclusively supplied to CymaBay in any contracts between CymaBay and the CMOs regarding Manufacture of Licensed Product ("***CMO Contracts***") in order to allow such CMO(s) to supply the Licensed Product to Kowa for use as permitted under this Agreement and (v) discuss with Kowa any other measures reasonably requested by Kowa in order to provide the benefit of such CMO Contracts to Kowa, provided that Kowa does not cause the breach by CymaBay of any applicable contractual obligations under the CMO Contracts in order to obtain such benefits. In addition, CymaBay will allow Kowa to have the benefit of all the applicable CMO Contracts as if Kowa was able to order product and to exercise any other rights thereunder, including by CymaBay placing orders for the Licensed Product under the terms of such CMO Contracts in quantities and at times reasonably requested by Kowa from time to time and reselling such Licensed Product to Kowa [ * ]. Kowa and CymaBay will negotiate with the CMOs to allow CymaBay (including its licensees) to retain access to and rights to use the CMC information, stability and other test results and improvements (including analytical and process improvements) made under such CMO Contracts by CymaBay ([ * ]) , for use outside the Territory. Until Kowa's entry into its own manufacture and supply agreements as needed for its Development work hereunder, CymaBay will cause the CMO Contracts to remain in effect and will perform obligations under such contracts as reasonably needed to provide additional clinical materials with respect to Kowa's Development of the Licensed Product pursuant to Section 2.2.1, at Kowa's written requests and in compliance with appropriate forecasting and ordering mechanisms that comply with the applicable CMO Contracts. As of the Effective Date, CymaBay confirms that it has a stock of [ * ], all of which CymaBay will provide [ * ] to Kowa. Such transfer will occur promptly after the Effective Date, and upon transfer Kowa will assume title and all risk of loss for all the transferred materials. For any new Licensed Product Manufactured pursuant to a CMO Contract for the Territory as the result of an order placed at the request of Kowa after the Effective Date, Kowa will be responsible for taking delivery, transporting, storing and paying the cost of such Licensed Product.

2.2.4 Kowa has the right to Manufacture, internally or by contract with Third Parties, the Licensed Product anywhere in the world, solely for Development and Commercialization in the Territory as permitted in this Agreement, and to import the Manufactured Licensed Product into the Territory for such use from anywhere in the world.

2.2.5 Kowa shall notify CymaBay within [ * ] days after NDA approval of the Licensed Product by the FDA of Kowa's or its Affiliate's or Sublicensee's decision whether or not to Launch. If Kowa (or its Affiliate or Sublicensee) decides to Launch, it shall use Commercially Reasonable Efforts to effect the Launch as soon as commercially practicable thereafter. If Kowa gives notice of the decision not to Launch, or does not provide any notice of a decision hereunder, then this Agreement automatically terminates under Section 8.2.4.

**2.3 Regulatory Affairs.**

2.3.1 CymaBay will, within [ * ] days after notice from Kowa, (a) transfer ownership of and rights under the INDs for the Licensed Product for the Territory for uric acid and for diabetes to Kowa or its Affiliate as directed by Kowa in its notice, and (b) with input and direction from Kowa, complete all relevant activities related to such transfer of the INDs, including the submission of relevant notices to the FDA, in form and substance reasonably satisfactory to Kowa, as required for Kowa or its Affiliate to assume such ownership and rights, as applicable. If requested by Kowa, CymaBay will also (i) promptly send letters (in form and substance satisfactory to Kowa) to the FDA and other applicable Regulatory Authorities in the Territory indicating that any other Regulatory Documentation relevant to the Territory are transferred to Kowa and that Kowa is the new owner of such Regulatory Documentation as of the Effective Date, (ii) send letters, within a reasonable amount of time after request by Kowa, to all applicable IRBs or other relevant entities and similar committees to direct Licensed Product-related communications in the Territory to Kowa commencing on the Effective Date, and (iii) provide to Kowa a copy of such letters.

2.3.2 As between the Parties, Kowa will have the sole right, at Kowa's sole cost and expense, to prepare, seek, submit and maintain all INDs, NDAs and other regulatory filings and Regulatory Approvals for the Licensed Product in the Territory, including preparing all reports necessary as part of a regulatory filing or Regulatory Approval and for all communications with Regulatory Authorities, in each case in the name of Kowa or its Affiliate or a Sublicensee.

2.3.3 As between the Parties, Kowa will have the sole right to apply for, secure and maintain Regulatory Approvals for the Licensed Product that may be available under the Laws of the Territory, including any Regulatory Exclusivity, in each case in Kowa's or its Affiliate's or Sublicensee's own name. CymaBay will cooperate in good faith with Kowa and such Affiliate and Sublicensee and take reasonable actions, at Kowa's reasonable request and Kowa's expense for any reasonable out-of-pocket expenses of CymaBay, to assist Kowa and such Affiliate and Sublicensee in obtaining such Regulatory Approvals and Regulatory Exclusivity in the Territory.

2.3.4 CymaBay will use reasonable efforts to cooperate with Kowa as reasonably requested from time to time, at Kowa's expense for any reasonable out-of-pocket expenses, in connection with Kowa seeking and obtaining Regulatory Approval for the Licensed Product in the Territory, including providing existing Data from within the Licensed Technology and adverse event reports, in the form mutually agreed by the Parties, as may be requested by Kowa from time to time, for disclosure to Regulatory Authorities.

2.3.5 Kowa will keep CymaBay reasonably informed (including through the JAC) of all submissions to Regulatory Authorities in the Territory regarding Development of or seeking Regulatory Approval of Licensed Product, and the status and progress of such submissions. CymaBay may comment on any such submissions, [ * ]. Once a submission is made to a Regulatory Authority in the Territory regarding Development of the Licensed Product, a full copy of the submission will be provided to CymaBay pursuant to the provisions of Section 2.3.9.

2.3.6 Kowa hereby grants, and will cause its Affiliates and Sublicensees to grant, CymaBay and its licensees of the Licensed Product outside the Territory, a "Right of Reference," as that term is defined in 21 C.F.R. § 314.3(b) (or any successor rule or any analogous Law existing or recognized outside of the United States), to, and a right to copy, access and otherwise use, all Kowa Regulatory Data, including all information and Data included in any regulatory filing, NDA, drug master file or other regulatory documentation owned or Controlled by Kowa or its Affiliate or its Sublicensees that relates to the Licensed Product within the Territory, to the extent necessary or useful for CymaBay or any CymaBay licensee of the Licensed Product outside the Territory to Develop or obtain Regulatory Approval for the Licensed Product outside the Territory, on the financial terms set forth in Section 2.3.8 below, and Kowa will provide a signed statement to this effect, if required by CymaBay or its licensee, in accordance with 21 C.F.R. § 314.50(g)(3) (or any successor or analogous law or regulation outside of the United States). CymaBay agrees that, prior to the first Regulatory Approval of an NDA for Licensed Product in the Territory, it and its Affiliates and licensees outside the Territory will not, without the prior written consent of Kowa (which consent can be withheld for any reason or no reason), (i) [ * ], (ii) [ * ] or (iii) [ * ]. CymaBay agrees that if it or its Affiliate or licensee performs non-clinical work on Licensed Product in the Territory, it shall inform Kowa in advance. Prior to such first Regulatory Approval, CymaBay may make request(s) to Kowa [ * ]. [ * ]. After such Regulatory Approval, and pursuant to the provisions of Section 2.3.8, Kowa shall provide to CymaBay copies of [ * ], which CymaBay (and its Affiliates and other licensees) may use in connection with Development and obtaining Regulatory Approval for the Licensed Product outside the Territory.

2.3.7 CymaBay hereby grants Kowa, and will cause its licensees and Affiliates with respect to the Licensed Product to grant, a corresponding Right of Reference to Kowa, its Affiliates and its Sublicensees (or its equivalent under applicable Law in the applicable jurisdiction), to, and a right to copy, access and otherwise use, all information and Data included in any regulatory filing, MAA, drug master file or other regulatory documentation owned or Controlled by CymaBay that relates to the Licensed Product outside the Territory, to the extent necessary or useful for Kowa or any Affiliate of Kowa or Sublicensee to Develop or obtain Regulatory Approval for the Licensed Product inside the Territory, on financial terms to be mutually agreed upon by the Parties (with the terms to be established pursuant to the provisions of Section 10.1.3 in the event the Parties cannot agree on such financial terms), and CymaBay will provide a signed statement to this effect, if required by Kowa, in accordance with 21 C.F.R. § 314.50(g)(3) (or any successor or analogous Law outside of the United States). Kowa agrees that if it or its Affiliate or Sublicensee performs non-clinical work on Licensed Product outside the Territory, it shall inform CymaBay in advance.

2.3.8 If CymaBay or its Affiliate or licensee, in its registration filing for Regulatory Approval of Licensed Product in a particular country outside the Territory, uses for demonstrating safety and efficacy any Kowa Raw Data or Kowa Regulatory Data owned by or received from Kowa, then CymaBay shall pay Kowa the following with respect to sales of such Licensed Product (by CymaBay or its Affiliate or licensee) in such country:

**(a)** if licensee makes the sales: [ * ] for licensee's sales of such Licensed Product in such country; or

**(b)** if CymaBay or its Affiliate makes the sales: [ * ] from its or its Affiliate's sales of such Licensed Product in such country;

*provided, however,* that the above payment obligations shall automatically terminate (as to all sales outside the Territory) once CymaBay has paid to Kowa an aggregate of $[ * ] under this Section 2.3.8.

2.3.9 Kowa will promptly provide CymaBay with copies of all material written or electronic communications received by it or its Affiliates or Sublicensees from, or forwarded or submitted by it or its Affiliates to, the Regulatory Authorities within the Territory with respect to Licensed Product, including all regulatory filings, IND, NDA, drug master file or other Regulatory Documentation Controlled by Kowa or its Affiliate or Sublicensee relating to Licensed Product in the Territory. Such material communications will be provided by Kowa to CymaBay within [ * ] Business Days of such receipt or forwarding. CymaBay will promptly provide Kowa with copies of all material written or electronic communications received by it or its Affiliates or licensees from, or forwarded or submitted by it or its Affiliates or its licensees to, the Regulatory Authorities outside of the Territory with respect to Licensed Product, including all regulatory filings, IND, NDA, drug master file or other Regulatory Documentation Controlled by CymaBay or its Affiliate or licensee relating to Licensed Product outside the Territory. Such material communications will be provided by CymaBay to Kowa within [ * ] Business Days of such receipt or forwarding.

2.3.10 To the extent practicable, Kowa will promptly provide CymaBay with prior written or email notice of all meetings, conferences and discussions that are scheduled with the FDA regarding the Licensed Product within [ * ] Business Days after Kowa or its Affiliate first receives notice of the scheduling of such meeting, conference or discussion. Subject to the confidentiality provisions set forth under Article 6, and to the extent permitted by the FDA, CymaBay may, upon Kowa's prior approval, send one representative of CymaBay to such meeting, conference or discussion solely in the capacity of an observer. The number of Kowa representatives and the identities of the representatives to be present at any such meeting, conference or discussion will be determined by Kowa in its good faith and reasonable judgment. Kowa will promptly forward to CymaBay copies of all meeting minutes and summaries of all such meetings, conferences and discussions with the FDA.

### 2.4 Joint Advisory Committee

As soon as practicably possible after the Effective Date, the Parties will establish a joint advisory committee (the "***JAC***") to facilitate communications between the Parties related to the Development and Commercialization of the Licensed Product in the Territory pursuant to this Agreement, including discussing Development progress, results and plans, regulatory matters, updates on improvements, Commercialization plans and results, and publication strategies. Each Party will designate an equal number of representatives, to be [ * ] each unless the Parties agree otherwise, with appropriate expertise to serve as members of the JAC. Each Party may replace its representatives on the JAC at any time upon notice to the other Party. The JAC will meet regularly or periodically in a manner appropriate to the issues under consideration by the JAC, but no less frequently than once per calendar quarter (unless the Parties otherwise agree). Meetings of the JAC will be held by telephone or videoconference. The JAC will only advise the Parties, and will not have decision-making authority or control over this Agreement or the Parties. Each Party will act in good faith and share through the JAC all pertinent information relating to Licensed Product Development and Commercialization results and progress, to facilitate each Party's respective activities as contemplated hereunder. The Parties' representatives shall discuss and prepare an agenda reasonably in advance of each JAC meeting and shall promptly prepare reasonably detailed minutes of each meeting (including summaries of the topics discussed and any conclusions and decisions, and any open issues or matters needing further work or attention). CymaBay may elect to terminate its participation in the JAC.

### 2.5 Safety Coordination Committee

The Parties shall establish a Safety Coordination Committee ("**SCC**") to coordinate the exchange of safety and adverse event information on an ongoing basis in the Territory and outside the Territory. The SCC shall create applicable timelines and scope for reporting (including safety and adverse event data collection and analysis) between Kowa and CymaBay (or applicable Affiliates, licensees and Sublicensees) that will (i) enable each Party to comply with its respective reporting requirements to Regulatory Authorities in their territory, and (ii) ensure worldwide safety surveillance. Each Party shall require its Affiliates, licensees and Sublicensees, as applicable, to also comply with the SCC. As between Kowa and CymaBay, CymaBay shall be responsible for establishing, holding and maintaining the global safety database for the Licensed Product. Kowa shall have the right to hold and maintain a parallel safety database for Licensed Product in the Territory as needed or required by Law. Promptly after a clinical trial on Licensed Product is commenced outside the Territory by CymaBay or its Affiliate or other licensee, the Parties shall enter into a reasonable and customary pharmacovigilance agreement to cover the exchange and reporting of safety information by all such parties.

## ARTICLE 3

## DILIGENCE AND EXCLUSIVITY

### 3.1 Efforts of Kowa.

Kowa will (a) carry out Development of the Licensed Product pursuant to the provisions of Section 2.2.1 and (b) upon receipt of Regulatory Approval for the Licensed Product for the Indications in the Territory use Commercially Reasonable Efforts to Commercialize the Licensed Product for treatment of the Indications; provided, however, that in the event Kowa breaches its obligations under Section 3.1(b), CymaBay will not be entitled to any equitable relief, and CymaBay may terminate this Agreement pursuant to Section 8.2.5. In the event that CymaBay materially breaches the terms of this Agreement, and such breach impedes Kowa's ability to perform its obligations under Section 2.2.1 or 3.1(b), then Kowa shall be relieved of performing such obligations to the extent that such breach impedes such performance (and will also be entitled to seek legal and equitable remedies with respect to such breach by CymaBay), but only for so long as such breach continues. Except as set forth in Section 2.2.1 and this Section 3.1, Kowa will not have any obligations to conduct Development or Commercialization of the Licensed Product, including any fiduciary obligations or implied duties.

### 3.2 Efforts of CymaBay.

CymaBay will use Commercially Reasonable Efforts to complete its ongoing Development activities for the Licensed Product set forth on **Schedule 4** initiated prior to the Effective Date for the Territory.

### 3.3 Exclusivity.

Except as permitted under this Agreement or as otherwise agreed in writing between the Parties, CymaBay agrees that it will not, and will cause its Representatives not to, in the Territory: (a) further research, Develop, or Manufacture (except as permitted under this Agreement, including in Section 4.3.3) or seek or maintain Regulatory Approval for, market, sell, distribute or otherwise Commercialize the Licensed Product, or otherwise compete with the Licensed Product in treating the Indications, or own a controlling interest in any entity that does so compete with the Licensed Product in treating the Indications, (*provided* that the foregoing covenants shall not apply to any entity that subsequently acquires CymaBay or to any affiliate of such entity or to a pre-existing program of an entity that merges with CymaBay or its Affiliate), or (b) grant or offer to grant a license under any Licensed Technology or Licensed Patents for use in any connection with Arhalofenate or any product containing Arhalofenate in the Territory, provided that this clause (b) shall not apply to a grant of license to Manufacture Licensed Product for use and sale outside the Territory, or to conduct non-clinical work on Licensed Product in the Territory in connection with Development of the Licensed Product outside the Territory as permitted herein, or (c) conduct any clinical development of Licensed Product in the Territory, except as permitted by Kowa in writing, or (d) cause any Third Party to perform any of the foregoing on CymaBay's behalf. CymaBay agrees that if it or its licensee performs non-clinical work on Licensed Product in the Territory, it shall inform Kowa in advance. CymaBay further agrees that it and its Affiliates will not promote, market, sell or distribute the Licensed Product in the Territory or export the Licensed Product from outside the Territory into the Territory and will use Commercially Reasonable Efforts to include and enforce express contractual restrictions in its contracts with licensee(s) outside the Territory, to prevent the export of the Licensed Product from outside the Territory into the Territory, and shall cease sale or distribution of Licensed Product to any customer or distributor that exports or otherwise transfers Licensed Product into the Territory. Kowa further agrees that it and its Affiliates will not promote, market, sell or distribute the Licensed Product outside the Territory or export the Licensed Product from the Territory to outside the Territory other than to conduct Development or Manufacture the Licensed Product as permitted under this Agreement and will use Commercially Reasonable Efforts to include and enforce express contractual restrictions in its contracts with Sublicensee(s) inside the Territory, to prevent the export of the Licensed Product from the Territory to outside the Territory, and shall cease sale or distribution of Licensed Product to any customer or distributor that exports or otherwise transfers Licensed Product outside the Territory.

## ARTICLE 4

## INTELLECTUAL PROPERTY MATTERS

**4.1 Ownership of Technology, Patents and Data.**

4.1.1 Inventorship of all inventions and discoveries conceived, reduced to practice, discovered or made pursuant to work conducted under this Agreement during the Term, whether or not patentable, will be determined in accordance with U.S. patent laws. Authorship of all works created pursuant to work conducted under this Agreement during the Term will be determined in accordance with U.S. copyright laws.

4.1.2 As between the Parties, CymaBay retains ownership of the Licensed Patents and the Licensed Technology that exist as of the Effective Date (subject to the terms and conditions of the DiaTex License Agreement and this Agreement).

4.1.3 As between the Parties, Kowa will be and is the sole owner of all (a) Improvement Technology with respect to which either (i) one or more of the Representatives of Kowa are deemed inventors or authors, as applicable, pursuant to Section 4.1.1 or (ii) subject to Section 4.1.4(b)(y), any combination of one or more of the Representatives of Kowa together with one or more of the Representatives of CymaBay are deemed co-inventors or co-authors, as applicable, pursuant to Section 4.1.1 (collectively, (i) and (ii), the "***Kowa Improvement Technology***"), (b) all Patents claiming any of the foregoing Improvement Technology (the "***Kowa Improvement Patents***") and (c) the Kowa Regulatory Data and Kowa Raw Data. CymaBay hereby assigns to Kowa all of CymaBay's and its respective Representative's(s') right, title and interest, whether existing now or arising in the future, in and to the Kowa Improvement Technology and the Kowa Improvement Patents. CymaBay will (x) execute all further instruments to document, record and perfect Kowa's sole ownership consistent with this Section 4.1.3 as reasonably requested by Kowa from time to time, and will cause each such Representative to do the same, and (y) make each such Representative available to Kowa and the Kowa Representatives as reasonably requested in connection with Kowa's or its Affiliate's protection thereof, including filing, prosecuting, maintaining and enforcing the Kowa Improvement Patents.

4.1.4 As between the Parties, CymaBay will be and is the sole owner of all (a) Improvement Technology with respect to which one or more of the Representatives of CymaBay are deemed inventors or authors, as applicable, pursuant to Section 4.1.1 (the "***CymaBay Improvement Technology***") and (b) Patents (x) claiming any of the foregoing Improvement Technology or (y) that are Enantiomer Patents (as defined in the DiaTex License Agreement) (collectively (x) and (y) above, the "***CymaBay Improvement Patents***").

4.1.5 As between the Parties, each Party shall solely own the Data generated from activities conducted by such Party or its Affiliates, Sublicensees or licensees. The Data Controlled by CymaBay (including any Data resulting from the CymaBay Development activities identified in **Schedule 4**) is included in the Licensed Technology and licensed to Kowa under Section 4.3.2, *provided that* all clinical Data relating to Licensed Product generated by or on behalf of CymaBay and its Affiliates and CymaBay's other licensees after the Effective Date is provided to Kowa under and subject to the terms of Section 2.3.7.

**4.2 Prosecution of Patents.**

4.2.1 As between the Parties, CymaBay will be responsible, subject to the terms below, for preparation, filing, prosecution, maintenance and seeking extensions of all Licensed Patents at [ * ] cost and expense and Kowa will provide CymaBay with reasonable cooperation related thereto at CymaBay's request and at [ * ] cost and expense. CymaBay will provide Kowa with a reasonable opportunity to comment on the preparation, filing, prosecution, maintenance and seeking extensions of the Licensed Patents, and CymaBay will consider in good faith all comments received from Kowa in a timely manner. If CymaBay reasonably determines that the continued prosecution or maintenance of particular Licensed Patent(s) is not justified (but excluding the Material Licensed Patents, for which CymaBay shall retain the above prosecution and maintenance obligations), then CymaBay may give [ * ] days' advance written notice to Kowa that it intends to cease such prosecution, maintenance or seeking extensions of the specified Licensed Patent(s). If Kowa gives notice within such [ * ] day period that it desires to undertake such prosecution and maintenance, then CymaBay will assign its rights in the subject Licensed Patents to Kowa. Absent such notice from Kowa, CymaBay may abandon the specified Licensed Patent(s) after the end of such period (but excluding any Material Licensed Patents).

4.2.2 To the extent permitted by applicable Law, CymaBay will seek extensions of applicable Licensed Patents with respect to Licensed Product at [ * ] cost and expense. CymaBay will be responsible for preparation, filing and maintenance of all Licensed Patents, [ * ].

4.2.3 As between the Parties, Kowa will be responsible for preparation, filing, prosecution, maintenance and seeking extensions of all Kowa Improvement Patents at Kowa's cost and expense, and CymaBay will provide Kowa with reasonable cooperation related thereto at Kowa's request and at Kowa's cost and expense. If Kowa reasonably determines that the filing of or continued prosecution or maintenance of particular Kowa Improvement Patent(s) is not justified, then Kowa shall give [ * ] days' advance written notice to CymaBay that it intends to cease such prosecution, maintenance or seeking extensions of the specified Kowa Improvement Patent(s). If CymaBay gives notice within such [ * ] day period that it desires to undertake such filing, prosecution and maintenance, then Kowa will assign the subject Kowa Improvement Patents to CymaBay. Absent such notice from CymaBay, Kowa may abandon the specified Kowa Improvement Patent(s) after the end of such period.

**4.3 License Grants to Kowa.**

4.3.1 Subject to the terms and conditions of this Agreement, CymaBay grants to Kowa an exclusive (even as to CymaBay), royalty-bearing license or, as the case may be, sublicense, including the right to sublicense or further sublicense (through multiple tiers), under all rights in the Licensed Patents to Exploit the Licensed Product in the Field in the Territory. Such rights include the rights, subject to the terms and conditions of this Agreement: (i) to make, have made, use, sell, offer for sale, distribute, import and market and otherwise Exploit the Licensed Product and (ii) to practice any methods or processes claimed in the Licensed Patents for any and all applications and purposes with respect to the Licensed Product in the Field in the Territory. CymaBay also grants to Kowa a non-exclusive, worldwide, royalty-bearing license or, as the case may be, sublicense, including the right to sublicense or further sublicense (through multiple tiers), under the Licensed Patents to (a) make or have made the Licensed Product or (b) conduct Development activities of Licensed Product (including pre-clinical, non-clinical and clinical testing), in either case anywhere in the world solely for Exploitation of Licensed Product under the foregoing license in the Territory.

4.3.2 Subject to the terms and conditions of this Agreement, CymaBay grants to Kowa an exclusive (even as to CymaBay), royalty-bearing license or, as the case may be, sublicense, including the right to sublicense or further sublicense (through multiple tiers), under all rights in the Licensed Technology in the Field solely (a) to reproduce, use, create derivative works of, distribute, display publicly and disclose the Licensed Technology in the Field in the Territory in order to file Regulatory Documentation with respect to, make, have made, use, sell, offer for sale, distribute, import and market and otherwise Exploit the Licensed Product in the Field in the Territory and (b) to practice any methods or processes in the Licensed Technology for any and all applications and purposes with respect to the Licensed Product in the Field in the Territory. CymaBay also grants to Kowa a non-exclusive, worldwide, royalty-bearing license or, as the case may be, sublicense, including the right to sublicense or further sublicense (through multiple tiers), under the Licensed Technology as reasonably necessary to (a) make or have made the Licensed Product or (b) conduct Development activities of Licensed Product (including pre-clinical, non-clinical and clinical testing), in either case anywhere in the world solely for Exploitation of Licensed Product under the foregoing license in the Territory.

4.3.3 Notwithstanding the exclusive grants in this Section 4.3, CymaBay retains all such rights under the Licensed Technology and Licensed Patents as needed for it (or its Affiliates or contractors) to (a) perform its obligations under this Agreement, (b) Manufacture the Licensed Product in the Territory and (c) conduct pre-clinical and non-clinical testing in the Territory, in either case (b) or (c) solely for Development and Commercialization activities outside the Territory, including Regulatory Approvals. Further, CymaBay retains all rights under the Licensed Technology and Licensed Patents for all applications and uses outside the scope of the licenses granted to Kowa hereunder.

**4.4 Right of First Negotiation.**

CymaBay hereby grants to Kowa a right of first negotiation with respect to any other license under any Intellectual Property of CymaBay (including the Licensed Technology and the Patents in the relevant jurisdiction equivalent to the Licensed Patents) covering the Licensed Product in the Field in Japan, subject to the following: Kowa's right set forth in the preceding sentence will be effective from the Effective Date for a period of [ * ]. If CymaBay at any time during such [ * ] period desires to offer any Person a license under any Intellectual Property of CymaBay (including the Licensed Technology and the Patents in Japan equivalent to the Licensed Patents) covering the Licensed Product in the Field in Japan, then CymaBay will promptly notify Kowa in writing of CymaBay's proposed terms and conditions thereof. Thereafter, if requested by Kowa by written notice within [ * ] days of the CymaBay notice, CymaBay and Kowa will negotiate in good faith the terms of such proposed license. If the Parties do not agree in writing on a binding full and definitive agreement concerning the same within [ * ] days after CymaBay's notice, then CymaBay's obligations and Kowa's rights under this Section 4.4 will terminate with respect to the license of Intellectual Property covering the Licensed Product in the Field in Japan, and thereafter CymaBay may proceed to enter into an agreement granting such license to other Persons.

**4.5 License Rights upon Bankruptcy.**

All licenses and similar use rights granted under or pursuant to any Section of this Agreement are and will otherwise be deemed to be for purposes of Section 365(n) of the United States Bankruptcy Code (Title 11, U.S. Code), as amended (the "***Bankruptcy Code***"), and of any comparable or similar laws and regulations in any other country or jurisdiction (collectively, such laws and regulations with the Bankruptcy Code, the "***Bankruptcy Laws***"), licenses of rights to "intellectual property" as defined in Section 101(35A) of the Bankruptcy Code. The Parties agree that the applicable Party, as licensee or sublicensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the applicable Bankruptcy Laws. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party under the applicable Bankruptcy Laws, the other Party will be entitled to a complete duplicate of (or complete access to, as appropriate) such intellectual property and all embodiments of such intellectual property (including supporting materials such as files relating to prosecution or enforcement), which, if not already in such other Party's possession, will be promptly delivered to it upon its written request thereof. Any agreements supplemental to this Agreement will be deemed to be "agreements supplementary to" this Agreement for purposes of Section 365(n) of the Bankruptcy Code and all similar provisions of the other Bankruptcy Laws.

**4.6 License Grant to CymaBay.**

Subject to the terms and conditions of this Agreement, Kowa grants to CymaBay a non-exclusive, fully paid up, royalty-free, license, including the right to sublicense or further sublicense (through multiple tiers), under the Kowa Improvement Technology and the Kowa Improvement Patents, solely to Develop, register, make, have made, use, sell, offer for sale, distribute, import and market and otherwise Exploit the Licensed Product solely outside the Territory and to practice any methods or processes claimed therein outside the Territory with respect to the foregoing activities with respect to the Licensed Product solely outside the Territory, and *provided further* that CymaBay (or its Affiliate or licensee) may exercise the applicable license rights granted in the foregoing within the Territory, but solely with respect to non-clinical Development efforts and Manufacturing activities to support Development or Commercialization of Licensed Product outside the Territory

**4.7 Enforcement of Patents.**

4.7.1 Each Party will promptly notify the other Party in the event of any actual, threatened or suspected infringement of any Licensed Patents or Kowa Improvement Patents.

4.7.2 As between the Parties, Kowa will be responsible for instituting litigation to cease, and/or to obtain damages for, infringement of the Licensed Patents in the Territory (including litigation relating to ANDA under the Hatch-Waxman Act). As between the Parties, any such litigation initiated by Kowa will be under Kowa's control (including the selection of legal counsel and the sole authority to settle or otherwise dismiss the litigation ) and at Kowa's cost and expense, provided that [ * ]. If required in order to establish standing to sue under any applicable Laws, CymaBay will join in any such litigation, upon Kowa's request and at [ * ] expense ([ * ]), and in any event, whether or not its participation is required for standing to sue, CymaBay will cooperate with and provide reasonable assistance to Kowa in the litigation at [ * ] expense. CymaBay will further cooperate with and provide reasonable assistance to Kowa, as reasonably requested by Kowa ([ * ]), in conducting pre-litigation diligence and other preparation for the litigation, including during the [ * ] period immediately prior to the earliest possible date for the filing of a first ANDA for a generic version of the Licensed Product. Any amount awarded by a judgment or paid under a settlement for such infringement will be allocated first to pay any and all of Kowa's ([ * ]) and CymaBay's ([ * ]) reasonable costs and expenses relating to the litigation, and then the remaining amount shall be paid to [ * ], up to the total amount of [ * ], and then the remainder, to the extent based on infringement of the Licensed Patents, will be allocated [ * ]. Kowa may not settle any such litigation in a manner that admits non-infringement, invalidity or unenforceability without CymaBay's prior written consent, such consent not to be unreasonably withheld.

4.7.3 As between the Parties, CymaBay will have the initial right, at its discretion, but subject to the below, to institute and conduct litigation to cease, and/or to obtain damages for, infringement outside the Territory of the Kowa Improvement Patents for which CymaBay (or its Affiliate or Representative) is a co-inventor. As between the Parties, any such litigation initiated by CymaBay will be under CymaBay's control (including the selection of legal counsel and the sole authority to settle or otherwise dismiss the litigation ) and at [ * ] cost and expense. If required in order to establish standing to sue under any applicable Laws, Kowa will join in any such litigation, upon CymaBay's request and at [ * ] expense ([ * ]), and in any event, whether or not its participation is required for standing to sue, Kowa will cooperate with and provide reasonable assistance to CymaBay in the litigation, to the extent requested by CymaBay and at [ * ] expense for [ * ]. Kowa will further cooperate with and provide reasonable assistance to CymaBay, as reasonably requested by CymaBay ([ * ]), in conducting pre-litigation diligence and other preparation for the litigation. Any amount awarded by a judgment or paid under a settlement for such infringement will be allocated first to pay any and all of CymaBay's and Kowa's ([ * ]) costs and expenses relating to the litigation, and then the remaining amount shall be [ * ]. If CymaBay does not commence a suit to enforce the applicable Kowa Improvement Patents against such infringement or take reasonable efforts to settle or otherwise secure the abatement of such infringement within [ * ] days of becoming aware of or receiving notice from Kowa of the existence of such infringement, then Kowa shall have the right, but not the obligation, to commence a suit or take action to enforce such Kowa Improvement Patents against such infringement at [ * ] cost and expense.

**4.8 Trademarks.**

As between the Parties, Kowa has the sole right in the Territory, at its sole cost and in its sole discretion, to (a) select the trademark(s), service mark(s), logo(s) and other source identifier(s) to be used on or in connection with the Commercialization of Licensed Product in the Territory (including its labeling), and (b) apply for, prosecute and maintain any registrations thereof in the Territory.

**4.9 Reservation of Rights.**

Except as expressly stated in this Agreement, no rights or licenses are granted under this Agreement by any Party or any of its Affiliates under any Intellectual Property of such Party or its Affiliates to the other Party or its Affiliates, whether by implication, estoppel or otherwise, and all such rights not expressly granted are hereby reserved by each Party and its Affiliates. Kowa covenants that it and its Affiliates will not use or practice any Licensed Patents or Licensed Technology outside of the Territory or for any use or purpose outside of the license rights expressly granted in this Agreement (other than the limited right to Manufacture and Develop Licensed Product outside the Territory as provided in Section 2.2.4, 4.3.1 and 4.3.2).

## ARTICLE 5

## LICENSE PAYMENTS

**5.1 Initial Payment.**

Within 15 days after the Effective Date, Kowa will pay to CymaBay a one-time, non-refundable and non-creditable upfront license fee in an aggregate amount equal to $5,000,000 in cash (the "***Initial Payment***").

**5.2 Development Milestone Payments.**

5.2.1 Kowa will notify CymaBay within [ * ] days after the first occurrence of any of the following events indicated below as a "Development Milestone" being achieved by Kowa, its Affiliate or its Sublicensee for the Licensed Product:

| Development Milestones | Milestone Payment (in millions) |
|---|---|
| [ * ] | $[ * ] |
| [ * ] | $[ * ] |
| [ * ] | $[ * ] |
| [ * ] | $[ * ] |
| **Total – Development Milestones** | **up to $[ * ]** |

5.2.2 Kowa will pay to CymaBay the "Milestone Payment" that corresponds to each such "Development Milestone" as specified in Section 5.2.1 within [ * ] days after the date that such milestone has been achieved.

5.2.3 In no event will a Milestone Payment in Section 5.2.1 (collectively, the "***Development Milestone Payments***") become payable more than once and in no event will the total Development Milestone Payments that become payable in accordance with this Section 5.2 exceed $[ * ].

**5.3 Royalty Payments on Net Sales.**

5.3.1 Kowa will pay royalties on all Net Sales of the Licensed Product in the Territory during the period commencing with the First Commercial Sale of the Licensed Product in the Territory and ending on the later of the (i) expiration of the last to exist Valid Claim covering the manufacture, use, offer for sale, sale or importation of the Licensed Product in the Territory and (ii) 10th anniversary of the First Commercial Sale (the "***Royalty Term***"). Upon expiration of the Royalty Term and payment of all royalties owed for sales of Licensed Product occurring prior thereto, the licenses to Kowa under this Agreement will be deemed irrevocable and non-terminable (and will survive termination of this Agreement for any reason), and upon payment of all royalties due based on Net Sales occurring during the Royalty Term in the Territory for the Licensed Product and of all Sales Milestone Payments achieved and owed under Section 5.4, such license will be deemed fully paid-up and royalty-free.

5.3.2 Kowa will incur royalties on Net Sales (based on the cumulative Net Sales of the Licensed Product in the Territory during the Royalty Term in a given calendar year) at the rates set forth below, as the same may be adjusted pursuant to Section 5.3.3:

| **Ranges of Calendar Year Net Sales of the Licensed Product in the Territory (in millions)** | **Royalty Rate applicable to each Range** |
|---|---|
| Net Sales up to and including $[ * ] | [ * ]% |
| Net Sales of more than $[ * ] | [ * ]% |

For illustrative purposes only, if Net Sales for a calendar year during the Royalty Term are $1.5 billion, the royalties payable by Kowa to CymaBay for such calendar year would be an aggregate of $[ * ], calculated as follows:

($[ * ] × [ * ]) + ($[ * ] × [ * ]) = $[ * ]

5.3.3 Upon the beginning of Generic Competition, the royalty rates set forth in Section 5.3.2 will be reduced by [ * ]%; provided, however, that if the foregoing Generic Competition is solely due to the launch of a generic equivalent by a Third Party based on an ANDA ("***At-Risk Launch***") and (a) the At-Risk Launch is subsequently the subject of a final and unappealable court order requiring the cessation of sales of the unlicensed product that is the subject of the At-Risk Launch, or (b) the Third Party ceases sales of the unlicensed product that is the subject of the At-Risk Launch, by agreement or otherwise, upon the cessation of sales of the unlicensed product by such Third Party, the [ * ]% reduction of the royalty rates will cease and the royalty rates will return to those set forth in Section 5.3.2 until the next occurrence of Generic Competition, in which case the [ * ]% reduction in royalty rates will be reapplied.

5.3.4 If either (a) Kowa, its Affiliate or its Sublicensee determines in good faith that in order to avoid a reasonable potential of infringement of a Blocking Third Party Patent Right it is advisable to obtain a license from the applicable Third Party under such Blocking Third Party Patent Right to Exploit the Licensed Product in the Territory, or (b) Kowa, its Affiliate or its Sublicensee of the Licensed Patents or the Licensed Technology is required by an order, judgment or similar action of a Governmental Authority to pay royalties or other amounts for the Exploitation of the Licensed Product in the Territory due to infringement of a Blocking Third Party Patent Right, then (c) Kowa may deduct from any of the royalty amounts due to CymaBay from Kowa under Section 5.3 of this Agreement for sales of such Licensed Product, [ * ]% of such amounts actually paid by Kowa, its Affiliate(s) or its Sublicensee(s) to such Third Party(ies) for the Blocking Third Party Product Rights, and provided that such deduction may not in any event reduce the amount of royalties owed for any particular quarter by more than [ * ]% of such amount otherwise owed.

5.3.5 Starting with the calendar quarter in which the first Net Sales occur for which a royalty is due under this Section 5.3, Kowa will provide a report to CymaBay with the Net Sales of the Licensed Product in the Territory and will make the royalty payment required pursuant to this Section 5.3 (such payments, collectively, the "***Royalty Payments***") within [ * ] days after the end of the each calendar quarter of the Term. Such royalty reports will provide the Net Sales during the reporting period, the applicable royalty rate(s), any deductions made pursuant to Sections 4.7.2, 5.3.3 and 5.3.4, and a calculation of the resulting royalty payment due through the end of the reporting period.

**5.4 Sales Milestone Payments.**

5.4.1 Kowa will notify CymaBay of the occurrence of any "Sales Milestone" set forth below within [ * ] days after the achievement of the corresponding "Threshold". The "Threshold" for purposes of such payments is the aggregate amount of Net Sales that have accrued during a calendar year of the Licensed Product in the Territory during the Royalty Term, and shall pay CymaBay the corresponding Sales Milestone Payment within [ * ] days of such notice.

| Sales Milestones | Sales Milestone Payment (in millions) | Threshold |
|---|---|---|
| Sales Milestone #1 | $[ * ] | $[ * ] |
| Sales Milestone #2 | $[ * ] | $[ * ] |
| **Total - Sales Milestones** | **Up to $[ * ]** | |

5.4.2 Kowa will only be required to pay each of Sales Milestones #1 and #2 (collectively, the "***Sales Milestone Payments***", and together with the Development Milestone Payments and the Royalty Payments, the "***Contingent Payments***") one time. Each Sales Milestone Payment will accrue on the first occurrence of aggregate Net Sales during a calendar year that equals or exceeds the applicable "Threshold", regardless of whether or not any other Sales Milestone is first achieved in the same calendar year.

**5.5 Payments for Sublicenses.**

During the Term, Kowa will pay to CymaBay [ * ]% of all Sublicense Revenue. Kowa will report the amount of Sublicense Revenue received and will pay the respective amount payable under the above on such Sublicense Revenue to CymaBay within [ * ] days after receipt by Kowa of the applicable Sublicense Revenue from the Sublicensees.

**5.6 Method of Payments.**

Each payment by Kowa to CymaBay pursuant to this Agreement will be made in U.S. dollars. The Initial Payment will be paid by electronic funds transfer in immediately available funds to such bank account(s) as CymaBay designated in writing to Kowa prior to the Effective Date. Each Contingent Payment will be made by electronic funds transfer in immediately available funds to such bank account as designated in writing by CymaBay to Kowa. If a payment is past due, Kowa will pay interest on such late payment, from the date the payment was due until fully paid, at an interest rate equal to [ * ].

**5.7 Inspection of Records.**

For at least [ * ] years after the end of any calendar year in which Net Sales occurred in the Territory upon which a Royalty Payment was due, Kowa and its Affiliates that have Net Sales will keep accurate books and records setting forth all the accounts regarding the sales, and the calculation of Net Sales resulting from such sales, of the Licensed Product in the Territory for each such calendar year. Kowa will, and will compel its Affiliates that have Net Sales to, permit CymaBay, using independent certified public accountants engaged by CymaBay and reasonably acceptable to Kowa, to examine all such books and records at any reasonable time, upon reasonable notice; provided, however, that Kowa will not be required to produce for inspection any such records relating to any period other than the [ * ] most recently ended calendar years. The foregoing right of examination (i) may be exercised only once during each calendar year [ * ] and (ii) may not be exercised with respect to any period that was previously subject to such inspection. Kowa (and its applicable Affiliates that have Net Sales) may require such accountants to enter into a reasonably acceptable confidentiality agreement and in no event will such accountants disclose to CymaBay or its Representatives any information, other than such as relates to the accuracy of the corresponding payments required to be made under this Agreement and any discrepancies in such payments. The opinion of said independent accountants regarding such reports and related payments will be binding on the Parties, other than in the case of manifest error. CymaBay will bear the cost of any such examination and review; provided, however, that if the examination shows an underpayment of any amounts due of more than [ * ]% of the amount due for an applicable calendar year, then Kowa will promptly reimburse CymaBay for its reasonable out-of-pocket expenses actually incurred in connection with such examination. Kowa will promptly pay to CymaBay the amount of any underpayment of amounts due revealed by any such examination plus interest as provided in Section 5.6. In addition, Kowa covenants that upon the exercise by CymaBay of its audit rights pursuant to this Section 5.7, Kowa will conduct contractually permitted audits of any Sublicensee's applicable books and records, to ensure that such reports are accurate and that it has received all royalties owed based on such sales.

**5.8 Tax Matters.**

5.8.1 "***Tax***" or "***Taxes***" means all taxes, charges, duties, fees, levies or other assessments, including income, excise, property, sales, consumption, use, value added, profits, license, withholding (with respect to compensation or otherwise), payroll, employment, net worth, capital gains, transfer, stamp, social security, environmental, occupation and franchise taxes, imposed by any Governmental Authority, and including any interest, penalties and additions attributable thereto, and all amounts payable pursuant to an agreement or arrangement with respect to taxes.

5.8.2 The Parties agree to cooperate and produce on a timely basis any Tax forms or reports reasonably requested by the other Party in connection with any payment made under this Agreement. Each Party further agrees to provide reasonable cooperation to the other Party, at the other Party's expense, in connection with any official or unofficial Tax audit or contest relating to payments made by the other Party under this Agreement.

5.8.3 Any payments made by a Party pursuant to this Agreement will not be reduced on account of any Taxes unless required by applicable Law. CymaBay will be responsible for paying any and all Taxes (other than withholding taxes required to be paid by Kowa under applicable Law) levied on account of, or measured in whole or in part by reference to, any payments it receives. Kowa will deduct or withhold from the payments any Taxes that Kowa is required to deduct or withhold under applicable Law. If, in accordance with the foregoing, Kowa withholds (as required by applicable Law) any amount from a payment to CymaBay, such withheld amount will be deemed paid by Kowa to CymaBay pursuant to this Agreement, and Kowa will (a) timely remit to CymaBay the balance of such payment; (b) timely remit the full amount withheld to the proper Governmental Authority; and (c) send to CymaBay written proof of remittance of the full amount withheld within [ * ] days following remittance. Kowa will use Commercially Reasonable Efforts to cooperate with any efforts by CymaBay to qualify for any exemption from such withholding taxes that are available under applicable Law.

## ARTICLE 6

## CONFIDENTIALITY

**6.1 Confidential Information.**

6.1.1 "***Confidential Information***" of a Party means any information regarding the business and operations of such Party or any of its Representatives, that is or has been disclosed (whether orally or in writing) by such Party or its Representatives (the "***Discloser***") to the other Party or its Representatives (the "***Recipient***"), in each case, to the extent that such information is not (a) as of the date of disclosure to the Recipient, known to the Recipient (other than pursuant to an obligation of confidentiality to the Discloser); (b) disclosed in published literature, or otherwise generally known to the public through no breach by the Recipient of this Agreement; (c) obtained by the Recipient from a Third Party free from any obligation of confidentiality to the Discloser; or (d) independently developed by the Recipient without use of the Confidential Information disclosed to the Recipient by the Discloser.

6.1.2 The Licensed Technology and unpublished Licensed Patents constitute the Confidential Information of CymaBay. All Kowa Improvement Technology, unpublished Kowa Improvement Patents, reports submitted to CymaBay by Kowa pursuant to Article 5 or information examined by CymaBay's auditors pursuant to Section 5.7, Kowa Regulatory Data and communications with Regulatory Authorities concerning the Licensed Product are, as between the Parties, the Confidential Information of Kowa. Moreover, [ * ], and *provided further* that, for clarity, the disclosure rights [ * ], and *further* that [ * ]. Notwithstanding the forgoing, CymaBay may disclose the Licensed Technology to potential and existing licensees of CymaBay for the Licensed Product outside the Territory provided that such licensee(s) are subject to confidentiality restrictions no less stringent than those set forth in this Article 6.

**6.2 Obligations of Confidentiality.**

6.2.1 Except as otherwise provided in this Agreement, during the Term and for [ * ] years thereafter, the Recipient (a) will keep confidential, and will cause its Representatives to keep confidential, all of the Confidential Information of the Discloser, and (b) will not disclose the Confidential Information of the Discloser to any Third Party. The Recipient agrees to take such action, and to cause its Representatives to take such action, to preserve the confidentiality of the Confidential Information of the Discloser as the Recipient would customarily take to preserve the confidentiality of the Recipient's own similar types of Confidential Information, but in no case using less than a reasonable degree of care.

6.2.2 Notwithstanding anything to the contrary in this Article, the Recipient and its Representatives may disclose the Confidential Information of the Discloser in connection with the exercise of rights granted to it hereunder to:

(a) Governmental Authorities, including Regulatory Authorities, to the extent reasonably deemed desirable or necessary to apply for, obtain or maintain INDs or Regulatory Approvals for the Licensed Product or file applications for, prosecute, maintain or enforce the Licensed Patents or the Kowa Improvement Patents or otherwise comply with Law;

(b) other Representatives, advisory boards, managed care organizations, non-clinical and clinical investigators, and contracted clinical research organizations and clinical trial sites, as needed in connection with Development or Commercialization of Licensed Product as contemplated hereunder; provided, however, that the Recipient enters into a confidentiality agreement or otherwise has an enforceable obligation of confidentiality with such Person before disclosing any of the Discloser's Confidential Information;

(c) in connection with prosecuting or defending litigation; provided, however, that the Recipient or Representative uses reasonable efforts to limit the dissemination of such information, including by use of protective orders and the like, as such Recipient would use for its own similar types of Confidential Information;

(d) in connection with the resolution of disputes under this Agreement; provided, however, that such Recipient will use reasonable efforts to limit the dissemination of such information, including by use of protective orders and the like, as such Recipient would use for its own similar types of Confidential Information; and

(e) in connection with filings required by security regulations and the rules and regulations of any securities exchanges upon which the Recipient's securities are traded; provided, however, that such Recipient will use reasonable efforts to limit the dissemination of such information, including by use of protective orders and the like, as such Recipient would use for its own similar types of Confidential Information.



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

**6.3 Transaction Publicity.**

Neither Party may issue a press release concerning this Agreement or the transactions contemplated hereby (including the achievement of milestone events and other significant progress in the Development or Commercialization of the Licensed Product) without the content of such release being approved in advance and in writing by the non-issuing Party, such approval not to be unreasonably withheld or delayed by the non-issuing Party. Without limiting the generality of the foregoing, concurrent with the execution of this Agreement, the Parties will agree upon mutually acceptable press releases to be issued promptly after the execution of this Agreement. Notwithstanding the first sentence of this Section 6.3, CymaBay shall have the right to make filings with Governmental Authorities which it determines, based on advice of counsel, are reasonably necessary to comply with applicable Laws, including regulations promulgated by securities exchanges and governmental agencies and, upon prior notice to Kowa, to make press releases concerning such filings and disclosing information only to the extent disclosed in such filings.

**6.4 Publication of Clinical Trial Results.**

Notwithstanding anything to the contrary in this Article, Kowa may publish any Data within the Licensed Technology or otherwise resulting from clinical trials conducted by or on behalf of Kowa on the Licensed Product without the consent of CymaBay. CymaBay may not publish any Data within the Licensed Technology existing as of the Effective Date or resulting from clinical trials conducted by or on behalf of Kowa on the Licensed Product without the consent of Kowa, which shall not be unreasonably withheld or delayed. Kowa shall not publish any clinical Data or results from any clinical trials conducted by CymaBay or its Affiliate or other licensee after the Effective Date, without the prior written consent of CymaBay, and CymaBay or its Affiliate or licensee may publish any such Data or results, at its discretion.

## ARTICLE 7

## REPRESENTATIONS, WARRANTIES AND COVENANTS

**7.1 CymaBay Representations and Warranties.**

CymaBay hereby represents and warrants to Kowa that, except as otherwise provided in a disclosure schedule attached hereto, as of the Effective Date:

7.1.1 CymaBay is a corporation duly incorporated, validly existing, and in good standing under the laws of the State of Delaware, has the corporate power and authority to execute and deliver this Agreement and to perform its obligations under this Agreement. The execution, delivery and performance of this Agreement by CymaBay have been duly and validly authorized and approved by proper corporate action on the part of CymaBay, CymaBay has taken all other action required by Law, its certificate of incorporation, bylaws or other organizational documents to authorize such execution, delivery and performance. This Agreement constitutes a legal, valid and binding obligation of CymaBay, enforceable against CymaBay in accordance with its terms, except as enforceability may be limited by applicable equitable principles or bankruptcy, insolvency, reorganization, moratorium or similar Laws affecting creditors' rights generally. There are no Affiliates of CymaBay.

7.1.2 Neither the execution and delivery of this Agreement nor the consummation of the transactions contemplated hereby will (a) result in any breach of, constitute a default (or an event that, with notice or lapse of time or both, would become a default) under, require any consent of or notice to any Person pursuant to, give to others any right of termination, amendment, modification, acceleration or cancellation of, allow the imposition of any fees or penalties, require the offering or making of any payment or redemption, give rise to any increased, guaranteed, accelerated or additional rights or entitlements of any Person or otherwise adversely affect any rights of CymaBay under, or result in the creation of any Lien on any of the Licensed Patents, the Licensed Technology or the Licensed Product pursuant to, any Contract or Governmental Authorization of CymaBay, (b) violate, conflict with or result in a breach of or constitute a default under any provision of the certificate of incorporation or bylaws or other organizational documents of CymaBay, (c) violate, conflict with or result in a breach of or constitute a default under any judgment, order, decree, rule or regulation of any court or Governmental Authority to which CymaBay or any of the Licensed Patents, the Licensed Technology or the Licensed Product is subject or may be bound or (d) violate, conflict with or result in a breach of any Laws or applicable regulations to which CymaBay or any of the Licensed Patents, the Licensed Technology or the Licensed Product is subject or may be bound.

7.1.3 To the Knowledge of CymaBay, CymaBay is and has been in compliance in all material respects with all Laws applicable to the ownership or use of the Licensed Patents and the Licensed Technology and the Manufacture, use, sale, offer for sale or importation of the Licensed Product. There is no, and within the past [ * ] years there has not been any, written action, claim (including regarding infringement of Intellectual Property), complaint, demand, suit, warning, assertion, proceeding, arbitration, citation, notice of non-compliance, summons, subpoena, request for information by a Governmental Authority, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or, to the Knowledge of CymaBay, verbally threatened against CymaBay or any of its Representatives relating to the Licensed Patents, the Licensed Technology or the Licensed Product, the Exploitation of the foregoing, or the transactions contemplated by this Agreement. There are no, and there have not been any judicial orders, writs, injunctions, decrees, judgments or stipulations in force against CymaBay or its Representatives (in their capacity as such) with respect to the Licensed Patents, the Licensed Technology or the Licensed Product. No claim or demand of any Person has been made in writing against CymaBay or to the Knowledge of CymaBay verbally threatened against CymaBay, nor is there any litigation that is pending or to the Knowledge of CymaBay verbally threatened against CymaBay, that (i) challenges the rights of CymaBay in respect of any of the Licensed Patents, the Licensed Technology or the Licensed Product, or (ii) asserts that the Manufacture, use, sale, offer for sale or importation of the Licensed Product or the processes used to make the Licensed Product (x) is, was or will be infringing or otherwise in violation of any Intellectual Property of any Person other than CymaBay or (y) is, was or will be required to pay any royalty, license fee, charge or other amount with regard to any Intellectual Property of any Person other than CymaBay.



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

7.1.4 No notice to or consent, approval, authorization, order, filing, registration or qualification of or with any court, Governmental Authority or any Person not a party to this Agreement is required to be made or obtained by CymaBay in connection with the execution and delivery of this Agreement or the consummation by CymaBay of the transactions contemplated hereby.

7.1.5 To the Knowledge of CymaBay, there is no prior art or other information, including any claim or assertion made by a third party, that would likely render any of the Licensed Patents unenforceable or invalid. Furthermore, to the Knowledge of CymaBay there is no prior art that, in its good faith understanding, would raise a substantial question as to the enforceability or validity of any of the Licensed Patents. CymaBay has disclosed to Kowa:

(a) all material scientific and technical information in CymaBay's possession or Control, including any publications, posters, CMC Information, pharmacokinetics data, and Regulatory Documentation relating to the Licensed Product or its Manufacture or use as such exists as of the Effective Date;

(b) correct and complete copies of all submissions, if any, of CymaBay to the FDA, or any other similar state or foreign Governmental Authority relating to the Licensed Product, and all amendments and supplements thereto, including all related pre-clinical and clinical data, and all related complaint information, adverse event information and safety information relating to the Licensed Product; and

(c) all material information existing as of the Effective Date relating to the Licensed Patents and the material Licensed Technology in each case necessary for Kowa to Manufacture, Develop, Commercialize and seek and obtain Regulatory Approval in the Territory for the Licensed Product. CymaBay shall, upon Kowa's reasonable request, provide further any invention disclosures, inventors' notebooks or other materials evidencing conception and/or reduction to practice, prior art search results and related memoranda and patentability opinions or evaluations, validity and enforceability searches and opinions or evaluations, freedom to operate searches and opinions or evaluations, and correspondence with and interview notes or other notes regarding communications with any of the inventor(s) and all other such material information in the possession or Control of CymaBay as of the Effective Date (including all material facts and publications that could constitute prior art, whether discovered before or after filing of the subject patent application) that, in such attorney(s)', agent(s)' or employees' reasonable judgment likely would be relevant to any Governmental Authority's consideration of whether any of the Licensed Patents are patentable/unpatentable, valid/invalid or enforceable/unenforceable, but *provided that* if any information therein is subject to attorney-client privilege, the Parties shall discuss in good faith whether, or under what circumstances, such privileged information shall be provided.

7.1.6 CymaBay has disclosed to the patent offices in the Territory in which CymaBay filed applications for the Licensed Patents all material information about which CymaBay was aware that is obligated under applicable Law to be so disclosed.

7.1.7 The clinical Data in the Licensed Technology disclosed or made available by CymaBay or any of its Representatives to Kowa prior to the Effective Date (the "Disclosed Information") has been true and correct in all material respects. To the Knowledge of CymaBay, the scientific, technical and other information relating to the Licensed Patents, the Licensed Technology and the Licensed Product disclosed or made available by CymaBay or any of its Representatives to Kowa prior to the Effective Date has been true and correct in all material respects. The experimental Data in the Disclosed Information is based upon actual experimentation conducted by or on behalf of CymaBay or its Representatives, and is otherwise in compliance in all material respects with all Health Care Laws in the Territory. The information disclosed or made available by CymaBay or any of its Representatives to Kowa prior to the Effective Date in the course of Kowa's due diligence investigation includes any material adverse information known to CymaBay or its Representatives relating to the Licensed Patents, the Licensed Technology or the Licensed Product.

7.1.8 Except for the INDs identified on **Schedule 2**, no IND has been filed by or on behalf of CymaBay or any of its Representatives with any Regulatory Authority in the Territory involving the Licensed Product or any of the Licensed Technology that relates to the Licensed Product. Neither CymaBay nor any of its Representatives is currently:

(a) working to file on his/her/its or another Person's behalf;

(b) advising or consulting with any Person in preparation for or in connection with filing; or

(c) assisting or encouraging any Person in connection with,

any submission to a Regulatory Authority in the Territory involving the Licensed Product or any of the Licensed Technology that relates to the Licensed Product.

7.1.9 To the Knowledge of CymaBay, the Manufacture, use, sale, offer for sale, and import of the Licensed Product described in the IND identified on **Schedule 2** does not, and after Regulatory Approval will not, infringe the Patent rights of any Person. The reproduction or disclosure of the Licensed Technology to Kowa pursuant to the terms of this Agreement, and Kowa's exercise of its rights hereunder in connection with Kowa's use of the Licensed Technology with respect to the existing Licensed Product, does not, and after the Effective Date will not, infringe the copyrights of, or misappropriate or otherwise violate the trade secret rights of any other Person. Neither CymaBay nor, to the Knowledge of CymaBay, any of its Representatives has received any written, or, to the Knowledge of CymaBay, verbal, allegation that the Manufacture, use, sale, offer for sale, and import in the Territory of Licensed Products or the use of the Licensed Technology in connection with the Licensed Product infringes or will infringe the Patents of any Third Party or infringes, misappropriates or otherwise violates or will infringe, misappropriate or otherwise violate the Intellectual Property rights of any Person.

7.1.10 CymaBay has delivered to Kowa a complete and accurate copy of the DiaTex License Agreement, including all amendments thereto. CymaBay has the unrestricted right (including the right under the DiaTex License Agreement) to grant to Kowa all rights in the Licensed Patents and the Licensed Technology that are being granted to Kowa under this Agreement upon the terms set forth herein. Neither CymaBay nor any of its Representatives has granted any license or sublicense to any rights in the Licensed Patents or the Licensed Technology to any Third Party that are in conflict with the rights granted to Kowa in this Agreement.

7.1.11 The Development and License Agreement between CymaBay and Ortho-McNeil, Inc. dated June 26, 2006, including the rights of Ortho-McNeil, Inc., has terminated prior to the Effective Date and there are no rights thereunder of Ortho-McNeil, Inc. relating to the Licensed Product, the Licensed Patents or the Licensed Technology that survived such termination and remain effective.

7.1.12 **Schedule 5** sets forth, with the owner, registration and application numbers and dates indicated, as applicable, all Licensed Patents that have issued or that have been applied for and are pending issuance with any Governmental Authority. All fees, taxes, annuities and other payments associated with filing, prosecuting, issuing, recording, registering or maintaining Licensed Patents have been paid in full in a timely manner to the proper Governmental Authority. Except as specified on **Schedule 5** otherwise, each Licensed Patent listed or required to be listed thereon is owned solely by CymaBay, is active, is, to the Knowledge of CymaBay, valid and enforceable (if granted), and the ownership of the entire right, title and interest is recorded (through its entire chain of title beginning with and including each inventor) with the applicable Governmental Authority solely in the name of CymaBay. CymaBay is not aware of and, to the Knowledge of CymaBay, CymaBay's Representatives that have been involved in prosecution of the Licensed Patents are not aware of, any information that, in its or their reasonable judgment, would likely render any of the granted Licensed Patents invalid or unenforceable and that is not part of the publicly available file history. CymaBay and, to the Knowledge of CymaBay, its Representatives have complied with all duties of candor owed to the patent office in the Territory with respect to the prosecution of each of the Licensed Patents.

7.1.13 CymaBay and, to the Knowledge of CymaBay, its Representatives have taken reasonable and customary measures to maintain and protect, as applicable, the confidentiality of the Confidential Information within the Licensed Technology.

7.1.14 All Representatives of CymaBay who are or were involved in the design, creation, conception, reduction to practice or development of the Licensed Patents or, to the Knowledge of CymaBay, the Licensed Technology or who were provided the composition of the Licensed Product Manufactured before the Effective Date using the Licensed Technology or claimed by the Licensed Patents, have executed written contracts (x) obligating them not to disclose the Confidential Information within the Licensed Technology, (y) specifying that all tangible materials that result from work performed by them on behalf CymaBay or its Affiliate is "work made for hire" under U.S. copyright laws or that they are otherwise obligated to assign to CymaBay all copyrights in such works, and (z) specifying that CymaBay solely owns and that such Representative assigns, immediately upon conception or creation, all other Intellectual Property rights relating to the Licensed Technology and Licensed Patents.

7.1.15 None of the Representatives of CymaBay is an inventor or author, based on work conducted pursuant to such Person's employment by or contractual engagement by CymaBay, or, to the Knowledge of CymaBay, based on work conducted independently of such employment or engagement, of any Technology or Patent necessary for the Development, Manufacturing, seeking or obtaining Regulatory Approval for, or Commercialization of the Licensed Product in the Territory that has not been assigned to CymaBay. None of the Representatives of CymaBay owns, in whole or in part, based on work conducted pursuant to such Person's employment by or contractual engagement by CymaBay, or, to the Knowledge of CymaBay, based on work conducted independently of such employment or engagement, or, to the Knowledge of CymaBay, has been granted a license to, any Technology or Patent necessary for the Development or Manufacturing of, seeking or obtaining Regulatory Approval for, or marketing, distribution, sale or other Commercialization of, the Licensed Product in the Territory that is not part of the Licensed Patents or Licensed Technology. No Person has alleged to CymaBay in writing, nor, to the Knowledge of CymaBay verbally alleged, nor, to the Knowledge of CymaBay, has any Person alleged to any of its Representatives that any Third Party owns, in whole or in part, any of the Licensed Technology or Licensed Patents, and to the Knowledge of CymaBay, there is no reasonable basis for any such allegation.

7.1.16 Other than pursuant to the DiaTex License Agreement, CymaBay has not been granted a license, covenant not to sue, immunity from suit or similar right from any Person under any Intellectual Property contained within, necessary for the Development, Manufacturing, seeking or obtaining Regulatory Approval for, or Commercialization of any Licensed Product or other Exploitation of any of the Licensed Technology or Licensed Patents in connection with the Licensed Product.

7.1.17 **Schedule 2** sets forth a true and complete list of all material agreements, which may include license agreements and Manufacturing or supply agreements, to which CymaBay is a party and that relate to the Licensed Product in the Field in the Territory. As soon as reasonably practicable after, but in any event within [ * ] days of, the Effective Date, CymaBay shall provide to Kowa all material pre-clinical and clinical trial agreements relating to Licensed Product Development for the Indications (the "Trial Agreements"), *provided that* for material clinical trial site agreements such provision may be within [ * ] days of the Effective Date (if needed for CymaBay to obtain complete copies of the applicable agreements). Except as described in **Schedule 2**, none of the agreements set forth on **Schedule 2** or the Trial Agreements: (i) requires a Third Party's consent to any assignment, licensing or sublicensing to Kowa, as provided in this Agreement, of any rights of CymaBay relating to Licensed Product obtained under such agreements; (ii) prevents CymaBay from assigning, licensing or sublicensing to Kowa, as provided in this Agreement, any rights of CymaBay relating to Licensed Product obtained under such agreements; or (iii) requires royalties to be paid by CymaBay in connection with the grant to Kowa of a license or sublicense as provided hereunder. Further, except as described in **Schedule 2**, under the agreements set forth on **Schedule 2**, or under the Trial Agreements, CymaBay has obtained either ownership or Control of rights to any Data and Intellectual Property developed or created under such agreements relating to Licensed Product that are necessary to the Development and Commercialization of Licensed Product, and CymaBay can license or sublicense, as applicable, such rights to Kowa as provided herein. True, correct and complete copies of the agreements set forth on **Schedule 2** and any documentation to be provided by CymaBay to Kowa pursuant to the provisions of Section 2.1.1 have been or will be provided to Kowa, and such agreements are in full force and effect and have not been modified or amended except as set forth in **Schedule 2**. Neither CymaBay nor, to the Knowledge of CymaBay, the other party to such agreements is in default with respect to a material obligation under, and none of such parties has claimed or, to the Knowledge of CymaBay, has grounds upon which to claim that the other party is in default with respect to a material obligation under, such agreements. CymaBay has not received any notice of breach under any of the agreements listed in **Schedule 2**. CymaBay has not waived or allowed to lapse any of its material rights under any agreements listed in **Schedule 2** with respect to the Licensed Product, and no such material rights have lapsed or otherwise expired or been terminated. To the Knowledge of CymaBay, the Licensed Patents which are subject to any agreements listed in **Schedule 2** were not and are not subject to any restrictions or limitations except for the specific terms of the applicable agreements set forth in **Schedule 2**.

7.1.18 CymaBay: (a) has not received any FDA Form 483, notice of adverse finding, warning letter, untitled letter or other correspondence or notice from the FDA or any other Governmental Authority alleging or asserting material noncompliance with any Laws or any Governmental Authorizations in connection with the Development of the Licensed Product; (b) has not received notice of any proceeding from the FDA or any other Governmental Authority or Third Party alleging that the Licensed Product is in violation of any Laws or Governmental Authorizations and to the Knowledge of CymaBay neither the FDA nor any other Governmental Authority or Third Party is considering any such proceeding; (c) has not received notice that the FDA or any other Governmental Authority has taken, is taking or intends to take action to limit, suspend, modify or revoke any Governmental Authorizations related to the Licensed Products; (d) has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, submissions and supplements or amendments with respect to its Development of the Licensed Product as required by any Laws or Governmental Authorizations; and (e) to the Knowledge of CymaBay its manufacturers and suppliers have at all times manufactured the Licensed Product supplied to CymaBay for use in human clinical trials in compliance with cGMP for the manufacture of products as are required by applicable Governmental Authorities or applicable Law in the relevant jurisdiction, including the rules and regulations of the FDA.

7.1.19 All pre-clinical and clinical investigations sponsored by CymaBay relating to the Licensed Product have been and are being conducted in material compliance with applicable Laws, including applicable cGCP requirements, and federal and state Laws, rules, regulations and guidance restricting the use and disclosure of individually identifiable health information. CymaBay has not received any notices or other correspondence from the FDA or any other Governmental Authority performing functions similar to those performed by the FDA with respect to any ongoing clinical or pre-clinical studies or tests relating to the Licensed Product requiring the termination, suspension or material modification of such studies or tests.

7.1.20 CymaBay's patent attorneys and agents currently engaged by CymaBay as of the Effective Date were involved in the filing, prosecution and maintenance of each of the Material Licensed Patents.

7.1.21 CymaBay has not (a) made an untrue statement of a material fact or fraudulent statement to the FDA or any Governmental Authority, (b) failed to disclose a material fact required to be disclosed to the FDA or any Governmental Authority, (c) committed any other act, made any statement or failed to make any statement, that (in any such case) establishes a reasonable basis for the FDA to invoke its Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities Policy or for any other state or foreign Governmental Authority to invoke any similar policy. CymaBay is not the subject of any pending or, to the Knowledge of CymaBay, threatened investigation by the FDA pursuant to its Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities Final Policy. Neither CymaBay, nor any of its Representatives, or, to the Knowledge of CymaBay, any of its collaboration partners, agents or subcontractors directly involved in the Development of the Licensed Product has been convicted of any crime or engaged in any conduct which has resulted or reasonably could result in debarment or disqualification by the FDA or any other Governmental Authority.

**7.2 Kowa Representations and Warranties.**

Kowa hereby represents and warrants to CymaBay that, as of the Effective Date:

7.2.1 Kowa is a corporation duly formed and validly existing under the laws of Delaware, has the power and authority to execute and deliver this Agreement and to perform its obligations under this Agreement. The execution, delivery and performance of this Agreement by Kowa has been duly and validly authorized and approved by proper corporate action on the part of Kowa, Kowa has taken all other action required by Law, and its organizational documents to authorize such execution, delivery and performance, and this Agreement constitutes a legal, valid and binding obligation of Kowa, enforceable against Kowa in accordance with their terms, except as enforceability may be limited by applicable equitable principles or bankruptcy, insolvency, reorganization, moratorium or similar Laws affecting creditors' rights generally.

7.2.2 Neither the execution and delivery of this Agreement nor the consummation of the transactions contemplated hereby will (a) result in any breach of, constitute a default (or an event that, with notice or lapse of time or both, would become a default) under, require any consent of or notice to any Person pursuant to, give to others any right of termination, amendment, modification, acceleration or cancellation of, allow the imposition of any fees or penalties, require the offering or making of any payment or redemption, give rise to any increased, guaranteed, accelerated or additional rights or entitlements of any Person or otherwise adversely affect any rights of Kowa under any Contract or Governmental Authorization of Kowa, (b) violate, conflict with or result in a breach of or constitute a default under any provision of the organizational documents of Kowa, (c) violate, conflict with or result in a breach of or constitute a default under any judgment, order, decree, rule or regulation of any court or Governmental Authority to which Kowa is subject or may be bound or (d) violate, conflict with or result in a breach of any Laws or applicable regulations to which Kowa is subject or may be bound.

7.2.3 There is no action, claim, complaint, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, request for information by a Governmental Authority, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or, to the knowledge of Kowa, threatened against Kowa or any of its Representatives relating to the Licensed Technology, the Licensed Patents, the Exploitation of the Licensed Product, or the transactions contemplated by this Agreement.

7.2.4 No notice to or consent, approval, authorization, order, filing, registration or qualification of or with any court, Governmental Authority or any Person not a party to this Agreement is required to be made or obtained by Kowa in connection with the execution and delivery of this Agreement or the consummation by Kowa of the transactions contemplated hereby.

**7.3 DISCLAIMER.**

EXCEPT FOR THE REPRESENTATIONS AND WARRANTIES EXPRESSLY STATED IN SECTIONS 7.1 AND 7.2, NO PARTY MAKES ANY REPRESENTATION OR WARRANTY OF ANY KIND WITH RESPECT TO ANY PRODUCTS, TECHNOLOGY, INTELLECTUAL PROPERTY RIGHTS OR ANY OTHER SUBJECT MATTER UNDER THIS AGREEMENT, AND EACH PARTY EXPRESSLY DISCLAIMS ALL SUCH OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT.

**7.4 CYMABAY COVENANTS**

7.4.1 CymaBay will maintain the DiaTex License Agreement in good standing and will not take any actions (or omit or fail to take any actions) which, after the expiration of any notice and/or cure periods, results in a termination or material breach of the DiaTex License Agreement, including exercising its option to terminate the DiaTex License Agreement under Sections 10.2 or 10.3 therein.

7.4.2 CymaBay agrees that it will not amend, modify or supplement the DiaTex License Agreement or agree to or consent to any amendment, modification or supplement to the DiaTex License Agreement in any manner which negatively affects the rights granted in this Agreement, without the prior written consent of Kowa.

## ARTICLE 8

## TERM AND TERMINATION

**8.1 Term.**

This Agreement will be effective as of the Effective Date and, unless terminated sooner pursuant to Section 8.2, will remain in effect until the expiration of the Royalty Term. The period from the Effective Date until expiration or termination (for any reason) of this Agreement in its entirety is the "***Term***" of this Agreement.

**8.2 Termination Rights.**

8.2.1 If CymaBay materially breaches or materially defaults in the performance or observance of any of its obligations under a material term of this Agreement, Kowa may terminate this Agreement as follows:

(a) if the breach was deliberate, then upon [ * ] days notice *provided that* CymaBay has not cured the breach within such [ * ]-day notice period;

(b) if the breach was not deliberate and can be cured within [ * ] days after notice thereof, then upon [ * ] days notice *provided that* CymaBay has not cured the breach within such [ * ]-day notice period; or

(c) if the breach was not deliberate but reasonably cannot be cured within [ * ] days after notice of breach, then upon [ * ] days notice unless before the end of such [ * ] days, CymaBay has discontinued the breaching act, used commercially reasonable efforts to cure the breach to the extent possible within such [ * ]-day period and has implemented all commercially reasonable steps to further cure such breach to the extent possible and to prevent further occurrences of such breach, and has cured such breach in any event by end of the [ * ] day period after giving such notice.

Notwithstanding the foregoing provisions of this Section 8.2.1, if CymaBay disputes that CymaBay materially breached any material term of this Agreement within the relevant [ * ] day period, this Agreement will not terminate unless such dispute is finally resolved pursuant to Section 10.1 where such resolution is that CymaBay did materially breach a material term of this Agreement and CymaBay failed to cure such material breach within the initial cure period.

8.2.2 If Kowa materially breaches or materially defaults in the performance or observance of any of its obligations under a material term of this Agreement, CymaBay may terminate this Agreement as follows:

(a) if the breach was deliberate, then upon [ * ] days notice *provided that* Kowa has not cured the breach within such [ * ]-day notice period;

(b) if the breach was not deliberate and can be cured within [ * ] days after notice thereof, then upon [ * ] days notice *provided that* Kowa has not cured the breach within such [ * ]-day notice period; or

(c) if the breach was not deliberate but reasonably cannot be cured within [ * ] days after notice of breach, then upon [ * ] days notice unless before the end of such [ * ] days, Kowa has discontinued the breaching act, used commercially reasonable efforts to cure the breach to the extent possible within such [ * ]-day period and has implemented all commercially reasonable steps to further cure such breach to the extent possible and to prevent further occurrences of such breach, and has cured such breach in any event by end of the [ * ] day period after giving such notice.

Notwithstanding the foregoing provisions of this Section 8.2.2, if Kowa disputes that Kowa materially breached any material term of this Agreement within the relevant [ * ] day period, this Agreement will not terminate unless such dispute is finally resolved pursuant to Section 10.1 where such resolution is that Kowa did materially breach a material term of this Agreement and Kowa failed to cure such material breach within the initial cure period.

8.2.3 Kowa may terminate this Agreement in its entirety (a) upon [ * ] advance written notice to CymaBay at any time within [ * ] of the Effective Date based on the results of Kowa's due diligence on CymaBay, the Licensed Patents, the Licensed Technology and the Licensed Product and (b) at any time thereafter for any or no reason upon [ * ] advance written notice to CymaBay. In the event Kowa terminates this Agreement pursuant to this Section 8.2.3, CymaBay will not be entitled to any damages or equitable relief due solely to such termination.

8.2.4 In the event that Kowa notifies CymaBay of Kowa's decision not to Launch or does not notify CymaBay of Kowa's decision to Launch within [ * ] days after NDA approval of the Licensed Product by the FDA, this Agreement will terminate [ * ] days after such event. In the event this Agreement terminates pursuant to this Section 8.2.4, CymaBay will not be entitled to any damages or equitable relief due solely to such termination.

8.2.5 In the event Kowa breaches its obligations under Section 2.2.1(b) or Section 3.1(b), CymaBay may terminate this Agreement. In the event CymaBay terminates this Agreement pursuant to this Section 8.2.5, CymaBay will not be entitled to any damages or equitable relief due solely to such termination, and further will not be entitled to damages or equitable relief for such breach to the extent provided in Section 2.2.1 or 3.1, as applicable.

**8.3 Effects of Expiration or Termination.**

8.3.1 Upon expiration of the Royalty Term, the rights and licenses granted to Kowa under Article 4 with respect to the Licensed Patents and the Licensed Technology will survive such expiration as further provided in Section 5.3.1. Upon expiration of this Agreement, the rights and licenses granted to Kowa under Article 4 with respect to the Licensed Patents and the Licensed Technology will survive such expiration on a perpetual basis. For clarity, termination by Kowa pursuant to Section 8.2.1 or CymaBay pursuant to Section 8.2.2. will be without prejudice to the applicable Party's remedies at law or in equity, including such Party's ability to receive damages or equitable relief with respect to thereto.

8.3.2 Upon termination of this Agreement during any such time as any clinical trials involving the Licensed Product are being conducted by Kowa, its Affiliates or their Representatives, Kowa and any other such Person will be entitled to complete the clinical trials to the extent reasonably necessary to comply with applicable Law.

8.3.3 Upon termination of this Agreement pursuant to Section 8.2.2, Section 8.2.3, Section 8.2.4 or Section 8.2.5:

(a) the rights and licenses granted to Kowa under Article 4 with respect to the Licensed Patents and the Licensed Technology will terminate and revert to CymaBay;

(b) Kowa will ensure that it and its Affiliates, and will use Commercially Reasonable Efforts to ensure that its Sublicensees, cease all Development and Commercialization of Licensed Products;

(c) Kowa will promptly return to CymaBay all copies containing or reflecting any Licensed Technology;

(d) Kowa will promptly return to CymaBay all amounts of Licensed Product (or active pharmaceutical ingredient) provided by CymaBay under Section 2.2.3;

(e) Kowa will provide CymaBay the opportunity to purchase any existing inventory of Licensed Product (and bulk active pharmaceutical agreement) made or purchased by Kowa, at Kowa's actual cost for such inventory;

(f) Kowa will return and assign to CymaBay the INDs and transfer and assign to CymaBay (i) any NDA arising therefrom for the Licensed Product, (ii) all Regulatory Documentation relating to the Licensed Product in the possession or Control of Kowa or its Affiliate and (iii) all Kowa Raw Data and Kowa Regulatory Data, including all pharmacovigilance Data (including adverse event Data) on the Licensed Product in the possession or Control of Kowa or its Affiliate; and

(g) at CymaBay's reasonable request [ * ], Kowa shall (i) subject to the provisions of Section 8.3.2, take reasonable steps to transfer any ongoing clinical trials to CymaBay and (ii) provide CymaBay with reasonable assistance with any inquiries and correspondence with Regulatory Authorities regarding the Licensed Product in the Territory, and (iii) cooperate reasonably with CymaBay in the transfer of the Licensed Product program back to CymaBay, and such assistance shall be limited to a period of [ * ] after such termination.

8.3.4 Upon expiration or termination of this Agreement, except for termination by Kowa pursuant to Section 8.2.1, the rights and licenses granted to CymaBay by Kowa under Section 4.6 will survive on a perpetual basis and also, in the case of such termination (other than pursuant to Section 8.2.1), such rights and licenses under Section 4.6 will automatically be deemed to be worldwide rights and licenses. Termination or expiration of this Agreement for any reason (a) will be without prejudice to CymaBay's right to receive all payments accrued before the effective date of such expiration or termination, including all payments on Net Sales for the Licensed Product occurring during the Royalty Term, and (b) will not release either Party from any liability, indebtedness, right to Losses or other obligation that already has accrued prior to such termination or expiration. Termination or expiration of this Agreement for any reason shall not constitute a waiver or release of, or otherwise be deemed to prejudice or adversely affect, any rights, remedies or claims, whether for damages or otherwise, that a Party may have hereunder based on breach by the other Party that arose prior to, or that arises out of or in connection with, such termination or expiration.

8.3.5 Upon termination of this Agreement pursuant to Section 8.2.1:

(a) the rights and licenses granted to Kowa under Article 4 with respect to the Licensed Patents and the Licensed Technology will terminate and revert to CymaBay;

(b) Kowa will ensure that it and its Affiliates, and will use Commercially Reasonable Efforts to ensure that its Sublicensees, cease all Development and Commercialization of Licensed Products; and

(c) Kowa will promptly return to CymaBay all copies containing or reflecting any Licensed Technology.

Notwithstanding the foregoing, if Kowa's right to terminate the Agreement pursuant to Section 8.2.1 arises, Kowa may, in lieu of terminating this Agreement, continue its license and pursue any other legal or equitable remedies to which it may be entitled, including its right of set-off against any subsequent payments which are owed to CymaBay pursuant to the provisions of Section 9.3.

8.3.6 The provisions of Articles 6, 8, 9, and 10 and Sections 4.1, 4.2.3 (until expiration of the Kowa Improvement Patents), 4.5 (solely as to CymaBay's and Kowa's respective surviving license and related rights), 4.7.3, 4.9, 5.7 (until the third anniversary of the termination or expiration of this Agreement), 5.8 and 7.3, as well as any other provisions that expressly are to survive or other provisions or defined terms referred to this Agreement or necessary to give them effect will survive termination or expiration of this Agreement and remain in force until discharged in full.

## ARTICLE 9

## INDEMNIFICATION

**9.1 Indemnification.**

9.1.1 CymaBay will indemnify, defend and hold Kowa and Kowa's Affiliates, and their respective directors, officers and employees (the "***Kowa Indemnitees***"), harmless from any and all Losses incurred by any of them in connection with any claim, suit or action by a Third Party (a "***Claim***") against the Kowa Indemnitees to the extent resulting from:

(a) the breach by CymaBay of any covenant of, or warranty or representation made by, CymaBay under this Agreement or the DiaTex License Agreement;

(b) the gross negligence, recklessness or wilful misconduct of CymaBay or any of its Representatives; or

(c) the Development, Manufacture, use, offer for sale, sale, importation or promotion of the Licensed Product by CymaBay or any of its Representatives, licensees or sublicensees following termination of the exclusive right to do so granted to Kowa under this Agreement.

Notwithstanding the foregoing, CymaBay will not be obligated to so indemnify, defend and hold Kowa or its Representatives harmless to the extent that such Losses or Claims are caused by (x) the breach of any covenant of, or warranty or representation made by, Kowa under this Agreement or (y) the gross negligence, recklessness or wilful misconduct of Kowa or any of its Representatives.

9.1.2 Kowa will indemnify, defend and hold CymaBay and its Affiliates and their respective officers, directors and employees (the "***CymaBay Indemnitees***") harmless from any and all Losses incurred by any of them in connection with any Claim by a Third Party against any CymaBay Indemnitee as a result of:

(a) the breach by Kowa of any covenant of, or warranty or representation made by, Kowa under this Agreement;

(b) the gross negligence, recklessness, or wilful misconduct of Kowa or any of its Representatives; or

(c) the Development, Manufacture, use, offer for sale, sale, importation or promotion of the Licensed Product by Kowa or any of its Representatives under this Agreement.

Notwithstanding the foregoing, Kowa will not be obligated to so indemnify, defend and hold CymaBay or its Representatives harmless to the extent that such Losses or Claims are caused by (x) the breach of any covenant of, or warranty or representation made by, CymaBay under this Agreement or (y) the gross negligence, recklessness or wilful misconduct of CymaBay or any of its Representatives.

**9.2 Indemnity Procedures.**

9.2.1 In the event that any Third Party asserts a Claim against a Kowa Indemnitee or CymaBay Indemnitee, as applicable, (the "***Indemnified Party***") with respect to any matter for which such Indemnified Party is entitled to indemnification under Section 9.1 (such Claim, a "***Third Party Claim***"), then the Indemnified Party will as soon as practicable notify the Party obligated to indemnify the Indemnified Party (the "***Indemnifying Party***") thereof and provide a copy of the relevant complaint or other claim and all other material information relating thereto; provided that no delay on the part of the Indemnified Party in notifying the Indemnifying Party and providing such documents and information will relieve the Indemnifying Party from any obligation under this Article 9 unless (and then only to the extent that) the Indemnifying Party is prejudiced by such delay.

9.2.2 The Indemnifying Party will have the right, exercisable by notice to the Indemnified Party within [ * ] days after receipt of notice from the Indemnified Party of the commencement of or assertion of any Third Party Claim, to assume direction and control of the defense, litigation, settlement, appeal or other disposition of the Third Party Claim (including the right to settle the claim solely for monetary consideration) with counsel selected by the Indemnifying Party, and the Indemnifying Party may do so without prejudice to its right to dispute whether such Claim involves a Third Party Claim subject to valid indemnification obligation hereunder. During such time as the Indemnifying Party is controlling the defense of such Third Party Claim, the Indemnified Party will cooperate, and will cause its Representatives to cooperate upon request of the Indemnifying Party and at Indemnifying Party's cost, in the defense or prosecution of the Third Party Claim, including by furnishing such records, information and testimony and attending such conferences, discovery proceedings, hearings, trials or appeals as may reasonably be requested by the Indemnifying Party. In the event that the Indemnifying Party does not notify the Indemnified Party of the Indemnifying Party's intent to defend any Third Party Claim within [ * ] days after the above notice thereof (including by affirmatively denying responsibility to defend the Third Party Claim), the Indemnified Party may (without further notice to the Indemnifying Party) undertake the defense thereof with counsel of the Indemnified Party's choice and (provided that such Claim is a Third Party Claim for which the Indemnifying Party is obligated under Section 9.1 to provide indemnification) at the Indemnifying Party's expense (including reasonable, out-of-pocket attorneys' fees and costs and expenses of enforcement or defense). The Indemnifying Party or the Indemnified Party, as the case may be, will have the right to join in (including the right to conduct discovery, interview and examine witnesses and participate in all settlement conferences), but not control, at its own expense, the defence of any Third Party Claim that the other Party is defending as provided in this Section 9.2.2.

9.2.3 The Indemnifying Party will not, without the prior written consent of the Indemnified Party, such consent not to be unreasonably withheld, enter into any compromise or settlement of the Third Party Claim that commits the Indemnified Party to take, or to forbear to take, any action or that imposes on such Indemnified Party any monetary obligation or admission of wrongdoing. The Indemnified Party will not have the right to settle any Third Party Claim, *unless* the Indemnified Party is solely defending such Third Party Claim as provided in Section 9.2.2, and in such case it may do so on such terms and conditions as it deems reasonably appropriate, to the extent such Third Party Claim involves equitable or other non-monetary relief, but will not have the right to settle such Third Party Claim to the extent such Third Party Claim involves monetary damages without the prior written consent of the Indemnifying Party. Each of the Indemnifying Party and the Indemnified Party will not make any admission of liability in respect of any Third Party Claim without the prior written consent of the other Party, and the Indemnified Party will use reasonable efforts to mitigate losses arising from the Third Party Claim.

**9.3 Set-Off Against Contingent Payments.**

If an amount damages has been awarded to Kowa by an arbitration (or a court of appropriate jurisdiction, if applicable) pursuant to a claim brought by Kowa for material breach by CymaBay pursuant to this Agreement, and if any Contingent Payment has not yet been fully paid pursuant to Article 5, Kowa may set-off such amounts of damages awarded from the payment of such Contingent Payment, notwithstanding any objection by CymaBay. The exercise of such right of set-off by Kowa, whether or not the claim is ultimately determined to be justified, will not constitute a breach of this Agreement, and *provided that* if such amount of damages (or any part thereof) is subsequently and finally determined (by arbitration or court order) not be have been owed by CymaBay, then Kowa shall pay such amount (or applicable part) to CymaBay pursuant to such determination.

**9.4 Limitation of Liability.**

IN NO EVENT WILL EITHER PARTY BE LIABLE UNDER THIS AGREEMENT TO THE OTHER PARTY FOR SPECIAL, INDIRECT, PUNITIVE OR INCIDENTAL OR CONSEQUENTIAL DAMAGES, WHETHER BASED IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, INCLUDING LOSS OF PROFITS OR REVENUE, SUFFERED BY A PARTY OR ANY OF ITS RESPECTIVE REPRESENTATIVES, EXCEPT IN THE EVENT OF AN INTENTIONAL AND WILFUL BREACH IN BAD FAITH OF ANY REPRESENTATION, WARRANTY, COVENANT OR AGREEMENT CONTAINED IN THIS AGREEMENT BY SUCH PARTY. THE FOREGOING SHALL NOT BE DEEMED TO LIMIT EITHER PARTY'S OBLIGATIONS UNDER SECTIONS 9.1 AND 9.2. THE FOREGOING LIMITATIONS ON DAMAGES SHALL NOT APPLY TO DAMAGES FOR BREACH OF THE OBLIGATIONS IN SECTION 6.2.

**9.5 Insurance.**

Each of Kowa and CymaBay will procure and maintain insurance issued by a reputable insurance company, which policy will insure against any and all claims, liabilities, costs, fees and expenses resulting from or caused by (or claimed to be resulting from or caused by) its (or its Representative's) use, Development or Commercialization of the Licensed Product in the Territory, with a limit of liability per occurrence of at least an amount equal to [ * ] U.S. Dollars (US$ [ * ]). It is understood that such insurance will not be construed to create a limit of either Party's liability with respect to their indemnification obligations under this Article 9. Each of Kowa and CymaBay will provide the other with written evidence of such insurance upon request. Each of Kowa and CymaBay will provide the other with written notice at least 30 days prior to the cancellation, non-renewal or material change in such insurance.

## ARTICLE 10

## MISCELLANEOUS

**10.1 Governing Law; Arbitration.**

10.1.1 Except as provided in Section 4.1.1, this Agreement will be governed by and construed in accordance with the laws of the State of New York, without reference to any rules of conflict of laws.

10.1.2 Any disputes arising with respect to the interpretation or enforcement of, or claims with respect to, any provision hereof will be finally settled under the then existing Rules of Arbitration of the International Chamber of Commerce. In any arbitration pursuant to this agreement, the award or decision will be rendered by three arbitrators appointed in accordance with said rules. The arbitration will be held in New York, New York, U.S.A, and will be conducted in the English language. The award or decision of the arbitrator pursuant to this Section 10.1.2 will be binding and conclusive upon the Parties, provided that enforcement of such award or decision may be obtained in any court having jurisdiction over the Party against whom such enforcement is sought.



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

10.1.3 In the event that the Parties are not able to reach agreement on the consideration to be paid by the applicable Party for the license and other rights granted under Section 2.3.7 within [ * ] days of commencing negotiations regarding such consideration, then at either Party's request such disagreement (the "Consideration Dispute") shall be made by an arbitration pursuant to the following terms: the Parties shall promptly jointly select an independent, neutral arbitrator who is experienced in licensing and drug product commercialization in the biotechnology and pharmaceutical field. If within [ * ] days after such commencement of the arbitration, in accordance with this Section, an arbitrator has not been appointed by the Parties, then each Party will select within an additional [ * ] days an individual who is independent and experienced in licensing and drug product commercialization in such field. The two individuals so appointed by the Parties will appoint an independent, neutral arbitrator who is experienced in licensing and drug product commercialization in the field and such three arbitrators will conduct the arbitration. The arbitration shall be conducted under the commercial arbitration rules of the American Arbitration Association, to the extent consistent with this Section 10.1.3. Within [ * ] days of the arbitrator's joint appointment by the Parties or appointment by the two individuals appointed by the Parties, as applicable, each Party will prepare and deliver to both the arbitrator and the other Party its last, best offer for the commercial consideration terms for resolution and decision on the Consideration Dispute (the "Proposal") and a memorandum (the "Support Memorandum") in support thereof. The arbitrator(s) will also be provided with a copy of the relevant provisions of this Agreement. Within [ * ] days after receipt of the other Party's Support Memorandum, each Party may submit to the arbitrator(s) (with a copy to the other Party) a rebuttal to the other Party's Support Memorandum. Neither Party may have communications (either written or oral) with the arbitrator(s) other than for the sole purpose of engaging the arbitrator or as expressly permitted in this Section. Within [ * ] days after the arbitrator's appointment, the arbitrator(s) will select, from the two Proposals provided by the Parties, the Proposal (the "Selected Proposal") that the arbitrator(s) believes is most consistent with the intent of the Parties when this Agreement was entered into and most accurately reflects industry norms for the amount of consideration (taking into account the contribution of the licenses granted) that would typically be agreed to in the context of the termination of similar corporate partnering agreements, and including taking into account the applicable Party's business prospects with respect to the Licensed Product covered by such license rights at that time and the relative contribution of value of such license grant as to such Licensed Product, consistent with applicable factors surrounding the issue in the Consideration Dispute. The decision of the arbitrator(s) shall be final, binding, and unappealable, and the Parties shall promptly proceed under the terms set forth in the Selected Proposal (provided that the applicable Party may decline to exercise the applicable license and rights, and thus not pay the applicable amounts covered by such Selected Proposal).

**10.2 Force Majeure.**

No Party will be held liable to the other Party nor be deemed to have defaulted under or breached the Agreement for failure or delay in performing any obligation under the Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God, or acts, omissions or delays in acting by any governmental authority (including by a Regulatory Authority, for any reason other than lack of due diligence, negligence or misconduct of the affected) or the other Party; *provided that* the affected Party will notify the other Parties of such force majeure circumstances as soon as reasonably practical, and will promptly undertake all reasonable efforts necessary to cure or avoid the effects of such force majeure circumstances and shall perform such obligation as soon as reasonably practicable after such circumstances abate or cease or can be reasonably avoided.

**10.3 Specific Performance.**

The Parties agree that irreparable damage would occur in the event any provision of Articles 2, 4 and 6 was not performed in accordance with the terms hereof and that the Parties will be entitled to seek specific performance of the terms hereof, in addition to any other remedy at law or equity without the necessity of demonstrating the inadequacy of monetary damages.

**10.4 Severability.**

If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein will not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties will in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

**10.5 Waivers.**

Any term or condition of this Agreement may be waived at any time by the Party or Parties that is entitled to the benefit thereof, but no such waiver will be effective unless set forth in a written instrument duly executed by or on behalf of the Party or Parties waiving such term or condition. Neither the waiver by any Party of any term or condition of this Agreement nor the failure on the part of any Party, in one or more instances, to enforce any of the provisions of this Agreement or to exercise any right or privilege, will be deemed or construed to be a waiver of such term or condition for any similar instance in the future or of any subsequent breach hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement will be cumulative and none of them will be a limitation of any other remedy, right, undertaking, obligation or agreement.

**10.6 Entire Agreement; Amendments.**

This Agreement sets forth the entire agreement and understanding between the Parties as to the subject matter hereof and supersedes all agreements or understandings, verbal or written, made between CymaBay, on the one hand, and Kowa, on the other hand, before the date hereof with respect to the subject matter hereof. None of the terms of this Agreement may be amended, supplemented or modified except in writing signed by the Parties.



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

**10.7 Construction.**

For purposes of this Agreement, (a) whenever the context requires: the singular number will include the plural, and vice versa; the masculine gender will include the feminine and neuter genders; the feminine gender will include the masculine and neuter genders; and the neuter gender will include the masculine and feminine genders, and "or" is not exclusive; (b) any rule of construction to the effect that ambiguities are to be resolved against the drafting Party will not be applied in the construction or interpretation of this Agreement; the words "include" and "including," and variations thereof, will not be deemed to be terms of limitation, but rather will be deemed to be followed by the words "without limitation;" (c) except as otherwise indicated, all references in this Agreement to "Sections," "Exhibits" and "Schedules" are intended to refer to Sections of this Agreement and Exhibits or Schedules to this Agreement; (d) the words "hereof," "herein" and "herewith" and words of similar import will, unless otherwise stated, be construed to refer to this Agreement as a whole and not to any particular provision of this Agreement; (e) unless the context otherwise requires, references to (i) any agreement (including this Agreement), Contract or Law are to the agreement, Contract or Law as amended, modified, supplemented or replaced from time to time, and to any section of any statute or regulation are to any successor to the section; and (ii) any Person include any successor to that Person or permitted successors and assigns of that Person; (f) the word "will" will be construed to have the same meaning and effect as the word "shall;" (g) the word "any" will mean "any and all" unless otherwise clearly indicated by context; (h) the word "or" is disjunctive but not mutually exclusive; (i) where a word or phrase is defined herein, each of its other grammatical forms will have a corresponding meaning; (j) no prior draft of this Agreement nor any course of performance or course of dealing will be used in the interpretation or construction of this Agreement; (k) no parole evidence will be introduced in the construction or interpretation of this Agreement unless the ambiguity or uncertainty in issue is plainly discernible from a reading of this Agreement without consideration of any extrinsic evidence; (l) although the same or similar subject matters may be addressed in different provisions of this Agreement, the Parties intend that, except as reasonably apparent on the face of the Agreement or as expressly provided in this Agreement, each such provision will be read separately, be given independent significance and not be construed as limiting any other provision of this Agreement (whether or not more general or more specific in scope, substance or content); (m) the table of contents, captions and headings contained in this Agreement are for convenience of reference only, will not be deemed to be a part of this Agreement and will not be referred to in connection with the construction or interpretation of this Agreement; and (n) all references to dollar amounts or "$" are references to U.S. dollars, and all payments hereunder will be made in U.S. dollars.

**10.8 Assignment; Successors.**

Neither this Agreement nor any of the rights, interests or obligations under this Agreement may be assigned or delegated, in whole or in part, by operation of law or otherwise, by a Party without the prior written consent of the other Party, and any such assignment without such prior written consent will be null and void; provided, however, that (i) Kowa may assign this Agreement or any or all of its rights or obligations hereunder to any Affiliate of Kowa without the prior consent of CymaBay, *provided that* Kowa shall nonetheless remain responsible for such Affiliate's complete performance of all obligations hereunder and liable for any breach thereof; and (ii) each Party may, without consent of the other Party, assign this Agreement in whole to its successor in interest in connection with the merger, acquisition, or sale of all or substantially all of the assets of such Party. In connection with any of the foregoing permitted assignments of this Agreement: (i) the assigning party shall provide written notice to the other Party of such assignment as soon as reasonably practicable; and (ii) the assignee thereof shall agree in writing delivered to the other Party to be bound as the assigning hereunder. Subject to the preceding provisions of this Section 10.8, this Agreement will be binding upon, inure to the benefit of, and be enforceable by, the Parties and their respective successors and permitted assigns.

**10.9 Independent Contractor.**

The relationship between CymaBay, on the one hand, and Kowa, on the other hand, is that of independent contractors. The Parties are not joint venturers, partners, principal and agent, employer and employee, and have no other relationship other than independent contracting parties. The Parties' obligations and rights in connection with the subject matter of this Agreement are solely and specifically as set forth in this Agreement, and the Parties acknowledge and agree that neither Party owes the other any fiduciary or similar duties or obligations by virtue of the relationship created by Agreement.

**10.10 Notices.**

All notices which are required or permitted hereunder will be in writing and sufficient if delivered personally, sent by e-mail (and promptly confirmed by personal delivery or internationally-recognized overnight courier) or sent by internationally-recognized overnight courier, addressed as follows:

**If to CymaBay:**
CymaBay Therapeutics, Inc.
7999 Gateway Blvd.
Suite 130
Newark, CA 94560 U.S.A.
Attention: Harold Van Wart, President and CEO
e-mail: [ * ]

**If to Kowa:**
Kowa Pharmaceuticals America, Inc.
530 Industrial Park Boulevard
Montgomery, AL 36117, U.S.A.
Attention: Ben Stakely
CEO and President
e-mail: [ * ]

(with a copy, which will not constitute notice)

Kowa Company, Ltd.
4-14, 3-Chome, Nihombashi-Honcho
Chuo-ku, Tokyo 103-8433, Japan
Attention: Tomoaki Kishi
Chief Manager
International Business Department and
Marketing Department (Ethical Products)
Pharmaceutical Division
e-mail: [ * ]



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

or to such other address as the Party to whom notice is to be given may have furnished to the other Parties in writing in accordance herewith. Any such notice will be deemed to have been given: (a) when delivered if personally delivered or sent by e-mail prior to 5:00 p.m. in the time zone of the receiving party on a Business Day, or if received after 5:00 p.m. in the time zone of the receiving party or on a day other than a Business Day, on the next Business Day; or (b) on the 3rd Business Day after dispatch if sent by internationally-recognized overnight courier. A Party may add, delete or change the person or address to which notices should be sent at any time upon written notice delivered to the other Parties in accordance with this Section 10.10.

**10.11 Third Party Beneficiaries.**

None of the provisions of this Agreement will be for the benefit of or enforceable by any Third Party, including any creditor of a Party. No Third Party will obtain any right under any provision of this Agreement or will by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against a Party.

**10.12 Performance by Representatives.**

To the extent that this Agreement imposes obligations on Representatives of a Party, such Party agrees to cause its Representatives to perform such obligations.

**10.13 Counterparts.**

This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. This Agreement may be executed by delivery of duly authorized and executed signature pages by facsimile or electronically in .PDF format.

**<Signature page follows on next page.>**



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

IN WITNESS WHEREOF the Parties hereto have caused this Agreement to be executed by their duly authorized officers to be effective as of the Effective Date.

CYMABAY THERAPEUTICS, INC.

By: _____
Name: _____
Title: _____

KOWA PHARMACEUTICALS AMERICA, INC.

By: _____
Name: _____
Title: _____

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

**Schedule 1**

**Definitions**

"***Affiliate***" means, with respect to a first Person, any other Person that directly or indirectly Controls, is Controlled by, or is under common Control with, such first Person. For purposes of this defintion, "Control" means the possession, directly or indirectly, of the power to direct or cause direction of the management or policies of another Person (whether through ownership of securities or other ownership interests, by contract or otherwise). A first Person will be presumed to Control another Person if such first Person actually owns or has beneficial ownership of at least 50% of the voting securities or other comparable equity interests of such other Person (whether directly, indirectly or pursuant to any option, warrant or other similar arrangement).

"***Agreement***" is defined in the preamble to this Agreement and further includes this Agreement as it may be amended or supplemented from time to time by the written agreement of the Parties.

"***ANDA***" means Abbreviated New Drug Application submitted under the FDCA.

"***Arhalofenate***" means the compound (-)-(R)-(4-chloro-phenyl)-(3-trifluoromethyl-phenoxy)-acetic acid 2-acetylamino-ethyl ester, also known as MBX-102, JNJ-39659100 and (-)-halofenate.

"***At-Risk Launch***" is defined in Section 5.3.3.

"***Bankruptcy Code***" is defined in Section 4.5.

"***Blocking Third Party Patent Rights***" means any particular claim in a Patent owned or controlled by a Third Party that, in the absence of a license thereunder, could reasonably be determined to be infringed by the Exploitation of the Licensed Product in the Territory pursuant to the licenses granted to Kowa hereunder, *but excluding* all Patent claims that claim delivery devices, formulations, excipients, gel-packs or other packaging, active ingredients that are not expressly and specifically claimed in the Licensed Patents, or methods of Manufacture of Licensed Product that are not expressly disclosed in the Licensed Technology, or methods of use of Licensed Product that are not specifically claimed in the Licensed Patents.

"***Business Day***" means a day, other than Saturday or Sunday, on which banks are open for business in San Francisco, California and Tokyo, Japan.

"***cGCP***" means, as applicable, the current good clinical practices set forth in the FDCA and its applicable implementing regulations at 21 C.F.R. Parts 50, 54, 56, 312 and 812, as applicable to investigational medicinal products for human use, and applicable substantially equivalent foreign Laws.

"***cGLP***" means, as applicable, the current good laboratory practices within the meaning of the FDCA and its applicable implementing regulations at 21 C.F.R. Part 58, and applicable substantially equivalent foreign Laws.

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

"***cGMP***" means, as applicable, the current practices, as amended from time to time, related to the manufacture of pharmaceutical products and any precursors thereto set forth in the FDCA and its applicable implementing regulations at 21 C.F.R. Parts 210-211, quality system requirements at 21 C.F.R. Part 820 for medical devices, and applicable substantially equivalent foreign Laws.

"***CMC Information***" means information related to the chemistry, manufacturing and controls of the Licensed Product, as specified by the FDA and other applicable Regulatory Authorities.

"***Combination Product***" means a pharmaceutical product containing a Licensed Product and at least one other clinically active ingredient that is not a Licensed Product combined into a single formulation (i.e., a fixed dose combination) or where such products are not formulated together but are sold together as a single product and invoiced as one product. Notwithstanding the foregoing, in no event shall the foregoing apply to any Licensed Product that is a combination (either a free combination, or a fixed dose combination, or otherwise) of Arhalofenate and febuxostat.

"***Commercialization***," with a correlative meaning for "Commercialize" and "Commercializing," means all activities undertaken before and after obtaining Regulatory Approvals relating specifically to the pre-launch, launch, promotion, detailing, medical education and medical liaison activities, marketing, pricing, reimbursement, sale and distribution of the Licensed Product, including strategic marketing, sales force detailing, advertising, medical education and liaison, and market and the Licensed Product support, and all customer support, Licensed Product distribution, invoicing and sales activities.

"***Commercially Reasonable Efforts***" means, with respect to the obligations and activities of the applicable Party, the carrying out of the subject obligations and activities using efforts and resources comparable to the efforts and resources that such Party or other pharmaceutical companies of then similar size and capitalization to such Party would typically devote to such obligations and activities for pharmaceutical products of similar market potential to Licensed Product at a similar stage in Development or product life, taking into account, using such Party's reasonable judgment, all scientific, commercial, and other appropriate conditions and factors that such Party or other such pharmaceutical companies would reasonably take into account, including issues of safety and efficacy, expected and actual cost and time to Develop, medical and clinical considerations, expected and actual profitability, expected and actual competitiveness of alternative Third Party products (including generic or biosimilar products) in the marketplace, the nature and extent of expected and actual market exclusivity (including patent coverage and regulatory exclusivity), the expected likelihood of Regulatory Approval, the expected and actual reimbursability and pricing, and the expected and actual amounts of marketing and promotional expenditures required; provided, however, that such efforts will include the right of such Party, using its reasonable judgment, to suspend, discontinue or decrease efforts and application of resources in circumstances where such suspension, discontinuation or decrease is consistent with the exercise of Commercially Reasonable Efforts.

"***Confidential Information***" is defined in Section 6.1.1.

"***Contingent Payments***" is defined in Section 5.4.2.

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

"***Contract***" means any contract, agreement, lease, sublease, license, sales order, purchase order, loan, credit agreement, bond, debenture, note, mortgage, indenture, guarantee, undertaking, instrument, arrangement, understanding or other commitment, whether written or oral, that is or was binding on any Person or any part of its property under applicable Law, whether or not terminated as of the Effective Date, including all amendments, supplements and correspondence related to any of the foregoing.

"***Control***" including, its correlative meanings, "Controls", "Controlled by" and "under common Control with" means, with respect to any material, information or intellectual property right, that a Party (a) owns or (b) has a license (other than a license granted to such Party under this Agreement) to such material, technology or Intellectual Property and, in each case, has the ability to grant to the other Party access, a license, or a sublicense (as applicable) to the foregoing on the terms and conditions set forth in this Agreement without violating the terms of any then-existing agreement or other arrangement with any Third Party.

"***CymaBay***" is defined in the preamble to this Agreement.

"***CymaBay Improvement Patents***" is defined in Section 4.1.4.

"***CymaBay Improvement Technology***" is defined in Section 4.1.4.

"***Data***" means all data, including CMC Information, non-clinical data and clinical data, generated by or on behalf of a Party or its Affiliates, licensees or Sublicensees (a) pursuant to activities conducted under this Agreement or (b) related to Licensed Product.

"***Development***" means, with respect to a product, any and all activities directed to pre-clinical, non-clinical and clinical testing and development, design and development planning, test method development and stability testing, toxicology, formulation, manufacturing process development, and manufacturing scale-up, qualification and validation, quality assurance/quality control, clinical trials, statistical analysis and report writing, interacting with key opinion leaders and scientific advisory boards, the preparation, submission and active management and maintenance of Regulatory Documentation for such product and interacting with Governmental Authorities regarding any of the foregoing, in each case whether before or after obtaining any Regulatory Approvals from a Governmental Authority. When used as a verb, "***Develop***" will mean to engage in Development.

"***Development Milestone Payments***" is defined in Section 5.2.3.

"***DiaTex***" is defined in the recitals to this Agreement.

"***DiaTex License Agreement***" is defined in the recitals to this Agreement.

"***Discloser***" is defined in Section 6.1.1.

"***Effective Date***" is defined in the preamble to this Agreement.

"***EMA***" means the European Medicines Agency or any successor agency thereto.

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"***Exploit***" means, collectively, research, Develop, have Developed, use, Manufacture, have Manufactured, sell, offer for sale, Commercialize, import, export, register and otherwise exploit.

"***FDA***" means the United States Food and Drug Administration or any successor agency thereto.

"***FDC***" means a fixed dose Licensed Product containing Arhalofenate together with one or more additional active pharmaceutical ingredients in fixed proportions in a single dosage form.

"***FDCA***" means the U.S. Federal Food, Drug, and Cosmetic Act, as amended, and the regulations promulgated thereunder.

"***Field***" means all fields of use.

"***First Commercial Sale***" means the first commercial sale in the Territory by Kowa or its Affiliate or Sublicensee of the Licensed Product to a Third Party intended for end use or consumption after Kowa's (or its Affiliate's or Sublicensee's) receipt of Regulatory Approval for the Licensed Product in the Territory. Use of the Licensed Product for promotional, sampling or compassionate use purposes that are customary in the prevailing pharmaceutical industry will not be considered a commercial sale hereunder.

"***Generic Competition***" means sales of a product in the Territory that is the same or substantially the same as the Licensed Product and that (a) is sold by an unauthorized Third Party that is not an Affiliate or Sublicensee of Kowa under a Regulatory Approval granted by a Regulatory Authority to the Third Party, and (b) was approved in reliance, in whole or in part, on the prior approval (or on safety or efficacy Data submitted in support of the prior approval) of the Licensed Product as determined by the applicable Regulatory Authority in the Territory.

"***Governmental Authority***" means any national, federal, regional, state, provincial, local, foreign, multinational, supra-national or other governmental authority or instrumentality, legislative body, court, administrative agency, commission or instrumentality, including any multinational authority having governmental or quasi-governmental powers, or any other industry self-regulatory authority and will include any Regulatory Authority.

"***Governmental Authorization***" means any (a) permit, license, certificate, franchise, concession, approval, consent, ratification, permission, clearance, confirmation, endorsement, waiver, certification, designation, rating, registration, qualification or authorization that is, has been or may in the future be issued, granted, given or otherwise made available by or under the authority of any Governmental Authority or pursuant to any Law, including an IND; or (b) right under any Contract with any Governmental Authority, and will include any Regulatory Approval.

"***Health Care Laws***" means all Laws regulating the design, development, testing, manufacturing, storing, labeling, packaging, transporting, marketing, importing, exporting, commercialization or reimbursement of pharmaceuticals, biologics, medical devices, diagnostics or combination products; or the relationships with health care professionals; or privacy matters, including, the FDCA, the Clinical Laboratory Improvement Amendments (42 U.S.C. § 263a), Medicare (Title XVIII of the Social Security Act) and Medicaid (Title XIX of the Social Security Act), the federal Anti-kickback Statute (42 U.S.C. § 1320a-7b(b)), the Stark Anti-Self-Referral Law (42 U.S.C. §§ 1395nn), the Anti-Inducement Law (42 U.S.C. § 1320a-7a(a)(5)), the civil False Claims Act (31 U.S.C. §§ 3729 et seq.), the administrative False Claims Law (42 U.S.C. § 1320a-7b(a)), the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. § 1320d et seq.), as amended by the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. § 17921(2) et seq.), the exclusion laws (42 U.S.C. 1320a-7), cGCP, cGMP and cGLP and all implementing regulations thereunder, and all applicable substantially equivalent foreign Laws.

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

"***Improvement Technology***" means any Technology that is (a) an improvement, modification or derivation of any of the Licensed Technology and (b) conceived, reduced to practice, discovered, made or created by any Party or any of its Representatives, whether solely or jointly.

"***IND***" means an Investigational New Drug Application submitted under the FDCA or an analogous application or filing with an Regulatory Authority outside the United States under any analogous foreign Law for the purposes of obtaining permission to conduct human clinical trials in such jurisdiction and, in relation to the Licensed Product, IND 111,713 for gout and IND 61,722 for diabetes.

"***Indemnified Party***" is defined in Section 9.2.1.

"***Indemnifying Party***" is defined in Section 9.2.1.

"***Indications***" means either or both of the following indications: (i) lowering of serum uric acid; and (ii) prevention of acute gout flares.

"***Initial Payment***" is defined in Section 5.1.

"***Intellectual Property***" means, in any and all jurisdictions throughout the world, all (a) Patents, (b) trademarks, service marks, trade dress, slogans, logos, symbols, trade names, brand names or other identifiers of source or goodwill recognized by any Governmental Authority, including registrations and applications for registration thereof and including the goodwill symbolized thereby or associated therewith, (c) Internet domain names and associated uniform resource locators and social media addresses and accounts, (d) copyrights, whether in published and unpublished works of authorship, registrations, applications, renewals and extensions therefor, mask works, and any and all similar rights recognized in a work of authorship by a Governmental Authority, (e) any trade secret rights in any inventions, discoveries, improvements, trade secrets and all other confidential or proprietary Information (including know-how, data (including Data), formulas, processes and procedures, research records, records of inventions, test information, and market surveys), and all rights to limit the use or disclosure thereof, (f) registered and unregistered design rights, (g) rights of privacy and publicity and (h) any and all other intellectual property rights recognized by any Governmental Authority under the Laws of any country throughout the world.

"***IRB***" an appropriately constituted institutional review board or ethics committee that has been formally designated to review and monitor biomedical research involving human subjects in accordance with regulations of the applicable Governmental Authority, including FDA regulations or analogous foreign regulations.

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"***JAC***" is defined in Section 2.4.

"***Knowledge of CymaBay***" means (a) the actual knowledge of [ * ] and (b) the actual knowledge of [ * ].

"***Kowa***" is defined in the preamble to this Agreement.

"***Kowa Improvement Patents***" is defined in Section 4.1.3.

"***Kowa Improvement Technology***" is defined in Section 4.1.3.

"***Kowa Raw Data***" means the raw Data resulting from any non-clinical, clinical and other studies performed by or on behalf of Kowa (including by its Affiliates and Sublicensees) with respect to the Licensed Product.

"***Kowa Regulatory Data***" means (a) all regulatory filings made by or on behalf of Kowa (including by its Affiliates and Sublicensees) with respect to the Licensed Product in the Territory and all reports generated by or on behalf of Kowa (including by its Affiliates and Sublicensees) related to the Licensed Product, including in the performance of its Development activities or regulatory activities set forth in Article 2, (b) any information contained in any regulatory filings with respect to the Licensed Product and (c) the results of any non-clinical, clinical or other studies or regulatory activities performed by or on behalf of Kowa (including by its Affiliates and Sublicensees) with respect to the Licensed Product (including tables, figures and listings "TFLs").

"***Launch***" means the commencement of commercial sales of the Licensed Product in the Territory after NDA approval of the Licensed Product by the FDA.

"***Law***" or "***Laws***" means any national, supranational, state, provincial, municipal or local statute, law, resolution, constitution, ordinance, code, regulation, rule, notice, regulatory requirement, interpretation, agency guidance, order, stipulation, determination, requirement or rule of law (including common law), code or edict issued, enacted, adopted, promulgated, implemented or otherwise put into law by or under the authority of any Governmental Authority, including Health Care Laws.

"***Licensed Patents***" means all Patents that (a) (i) are Controlled by CymaBay or its Affiliates as of the Effective Date, (ii) become Controlled by CymaBay or its Affiliates during the Term and (b) claim the composition of matter or manufacture of the Licensed Product or the use of the Licensed Product in the Field, or are otherwise necessary or useful for the Development or Commercialization of the Licensed Product in the Field in the Territory, including the patents and applications listed on Schedule 5 and all CymaBay Improvement Patents.

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

"***Licensed Product***" means any pharmaceutical product (a) containing Arhalofenate as an active ingredient, whether alone or in combination with other active pharmaceutical ingredients and (b) that is covered by a Valid Claim or is made or used using the Licensed Technology.

"***Licensed Technology***" means all Technology that (a) (i) is Controlled by CymaBay or its Affiliates as of the Effective Date or (ii) becomes Controlled by CymaBay or its Affiliates during the Term and (b) is necessary or useful for the Development or Commercialization of the Licensed Product in the Field in the Territory, including the Technology and Regulatory Documentation listed on **Schedule 2** and all CymaBay Improvement Technology.

"***Liens***" means any lien, pledge, hypothecation, charge, mortgage, security interest, encumbrance, claim, option, right of first refusal, preemptive right, community property interest, conditional or installment sale agreement, encumbrance, charges or other claims of third parties of any kind, or restriction of any nature (including any restriction on the voting of any security, any restriction on the transfer of any security or other asset, any restriction on the receipt of any income derived from any asset, any restriction on the use of any asset and any restriction on the possession, exercise or transfer of any other attribute of ownership of any asset).

"***Losses***" means any and all costs, expenses, claims, losses, liabilities, damages, fines, royalties, penalties, deficiencies, interest, settlement amounts, awards, and judgments, including any and all reasonable, out-of-pocket costs and expenses properly incurred as a result of a claim (including reasonable, out-of-pocket attorneys' fees and all other expenses reasonably incurred in investigating, preparing or defending any litigation or proceeding, commenced or threatened), in each case, net of any insurance recovery (net of increased or retroactive premiums) received in connection with any of the foregoing.

"***MAA***" or Marketing Authorization Application means the regulatory filing made under foreign health regulation and Law in order to obtain a product license to manufacture, distribute and sell a drug product in the European Union and other countries or jurisdictions outside the Territory. It is roughly equivalent to an NDA as used in the U.S.

"***Manufacture***" means, with respect to the Licensed Product, those manufacturing-related activities that support the research, Development (including the seeking and obtaining of Regulatory Approvals) and Commercialization of the Licensed Product, including developing the process for the Manufacture of clinical and commercial quantities of the Licensed Product manufacturing scale-up, validation, qualification and audit of clinical and commercial manufacturing facilities, bulk production and fill/finish work, related quality assurance technical support activities and CMC (chemistry, manufacturing and controls) activities, and including, in the case of a clinical or commercial supply of the Licensed Product, the synthesis, manufacturing, processing, formulating, packaging, labeling, holding, quality control testing, stability testing, release testing and release of the Licensed Product.

"***Material Licensed Patents***" means [ * ].

"***NDA***" means a New Drug Application submitted under the FDCA.

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

"***Net Revenues***" means: (a) the amount equal to (i) any royalty payments received by CymaBay or its Affiliates from a licensee, pursuant to or in connection with a license of the rights to Commercialize the Licensed Product outside the Territory granted by CymaBay or its Affiliate to such licensee, based on such licensee's sales of Licensed Product, less (ii) all royalties payable by CymaBay or its Affiliate to a licensor of CymaBay, or such Affiliate, based on such sales of Licensed Product by such licensee; and (b) any sales milestone payments received by CymaBay or its Affiliates from any such licensee based on such licensee's sales of Licensed Product.

"***Net Sales***" means, with respect to sales of the Licensed Product by Kowa, its Affiliates or its Sublicensees, the gross amounts invoiced for sales of the Licensed Product in the Territory to customers during the applicable period in bona fide arms' length transactions, less the following deductions which are actually incurred or allowed with respect to such sales of the Licensed Product using U.S. generally accepted accounting principles ("GAAP") consistently applied, and not otherwise recorded by or reimbursed to the selling party or its Affiliates:

(i) Customary trade, quantity and cash discounts;

(ii) Customary discounts, refunds, rebates (including customer inventory management fees), chargebacks, and retroactive price adjustments;

(iii) Accrued product returns and allowances;

(iv) Any tax imposed on the production, sale, delivery or use of the Licensed Product, including sales, use, excise or value added taxes;

(v) Allowance for distribution expenses commercially incurred in the distribution from Kowa and its Affiliates to any customer; and

(vi) Any similar and customary allowance, discount or deduction in the pharmaceutical industry in accordance with U.S. GAAP, consistently applied.

All amounts described above will be determined from the true and correct books and records of Kowa and its Affiliates that have Net Sales using its current standard procedures and methodology, maintained in accordance with U.S. GAAP, consistently applied.

In no event will any particular amount identified above be deducted more than once in calculating Net Sales. Net Sales will not include transfers or dispositions of the Licensed Product for charitable, promotional, pre-clinical, clinical, regulatory or governmental purposes. Net Sales will not include sales or other transfers between or among Kowa, its Affiliates or its Sublicensees, but the subsequent resale of such Licensed Product to a Third Party shall be included within the computation of Net Sales.

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

If the Licensed Product is sold as a Combination Product:

Net Sales of Combination Products shall be calculated by multiplying Net Sales of such Combination Product by a fraction A/A+B, where A is the sale price of the Licensed Product portion of such Combination Product when sold separately in the Territory and B is the sale price of the other product in such Combination Product when sold separately in the Territory; provided, however, that if the Licensed Product portion of such Combination Product or any of the other products in such Combination Product is not then sold separately in the Territory, then the Parties shall determine Net Sales for such Combination Product by mutual agreement based on the relative contribution of the Licensed Product and the other active ingredient(s) in the Combination Product.

"***Party***" and "***Parties***" are defined in the preamble to this Agreement.

"***Patent***" means all classes and types of patents and patent applications (including provisionals, non-provisionals, originals, priority, utility, design, divisionals, continuations, continuations-in-part, extensions, re-examinations, reissues and all other pre-grant and post-grant forms), utility models and applications for utility models, inventor's certificates and applications for inventor's certificates, and other indicia of exclusive rights to an invention or discovery issued by or applied for with any Governmental Authority.

"***Phase 3 Clinical Trials***" means a human clinical trial of the Licensed Product for the Indications on a sufficient number of subjects in an indicated patient population that is designed to establish that the Licensed Product is safe and efficacious for its intended use and to determine the benefit/risk relationship, warnings, precautions, and adverse reactions that are associated with such product in the dosage range to be prescribed and that is intended to support an NDA of such Licensed Product as described in **Schedule 3**.

"***Person***" means any natural person, any form of for-profit or non-profit business entity recognized by any Governmental Authority, including any corporation, partnership, limited liability company, association, trust or other legal entity, or any Governmental Authority.

"***Recipient***" is defined in Section 6.1.1.

"***Regulatory Approval***" means, with respect to any jurisdiction, any and all approvals, licenses, registrations or authorizations of a Regulatory Authority (including an NDA) that are legally necessary for the manufacture, distribution, importation, use, marketing, offer for sale or sale of a pharmaceutical in such jurisdiction, including, as applicable, any pricing or reimbursement approval, pre- and post-approval marketing authorizations (including any prerequisite manufacturing approval or authorization related thereto), and approval of product labelling.

"***Regulatory Authority***" means, with respect to any country or jurisdiction, the relevant Governmental Authority having responsibility for granting Regulatory Approval in such country or jurisdiction, including the FDA in the U.S. and the EMA in the European Union, or any of their respective successors and including any applicable IRBs.

"***Regulatory Documentation***" means all (a) applications (including all INDs registrations, licenses, authorizations, and approvals (including Regulatory Approvals), (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all regulatory drug lists, advertising and promotion documents, adverse event files, and complaint files, and (c) clinical Data and other Data contained or relied upon in any of the foregoing, in each case ((a), (b), and (c)) relating to the Licensed Product.

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

"***Regulatory Exclusivity***" means, with respect to the Territory, an additional market protection, other than Patent protection, granted by a Regulatory Authority in the Territory that confers an exclusive commercialization period during which Kowa, its Affiliate or its Sublicensee has the exclusive right to market and sell the Licensed Product in the Territory through a regulatory exclusivity right (e.g., new chemical entity exclusivity, new use or indication exclusivity, new formulation exclusivity, orphan drug exclusivity, pediatric exclusivity or any applicable Data exclusivity).

"***Renal PK Study***" means the pharmacokinetic study of the Licensed Product (arhalofenate) in patients with impaired renal function as specified and confirmed by Kowa.

"***Representatives***" means, with respect to a Party, the Affiliates of such Party, and each of such Party's and its Affiliates' respective officers, directors, managers, employees, consultants, and contractors.

"***Royalty Payments***" is defined in Section 5.3.5.

"***Royalty Term***" is defined in Section 5.3.1.

"***Sales Milestone Payments***" is defined in Section 5.4.2.

"***Specified Studies***" is defined in Section 2.2.1.

***"Sublicense Revenue"*** means any payments received by Kowa or its Affiliate(s) as initial payments or milestone payments or other sublicense fees or payments (but excluding royalties) from its or their respective Sublicensees pursuant to or in connection with a sublicense agreement in consideration for the rights granted to commercialize the Licensed Product.

"***Sublicensee***" means any Third Party to which Kowa grants a sublicense, directly or indirectly through its Affiliate, under any of the rights within the Licensed Patents or Licensed Technology.

"***Tax***" or "***Taxes***" is defined in Section 5.8.1.

"***Technology***" means all knowledge of a technical, scientific, business and other nature, including information, know-how, technology, means, methods, processes, practices, formulae, formulations, compositions, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data (including Data), results, prototypes, samples and other materials, and other biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols, reagents and Regulatory Documentation; in each case (whether or not confidential, proprietary, patented or patentable, of commercial advantage or not) in written, electronic, graphical or other documentary form.

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

"***Term***" is defined in Section 8.1.

"***Territory***" means the United States of America (including all possessions and territories thereof).

"***Third Party***" means any person or entity other than a Party.

"***Third Party Claim***" is defined in Section 9.2.1.

"***Valid Claim***" means either (a) an issued, unexpired claim within the Material Licensed Patents that has not been permanently declared invalid or unenforceable by a Governmental Authority of competent jurisdiction or (b) a pending claim within the Material Licensed Patents that has not been pending more than [ * ] from the date of filing of the first patent application to which such pending claim claims priority and that has not been finally determined to be unpatentable by a Governmental Authority of competent jurisdiction.

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

**Schedule 2**

**Certain Licensed Technology (as of the Effective Date)**

All of the following to the extent in the possession or control of CymaBay as of the Effective Date:

[ * ]

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

**Schedule 3**

**Specified Studies**

**[ * ]**

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

**Schedule 4**

**CymaBay Development Activities**

[ * ]

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

**Schedule 5**

**Licensed Patents (as of Effective Date)**

{Omitted content comprises approximately 7 pages}

**[ * ]**

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

**Disclosure Schedule**

{Omitted content comprises approximately 3 pages}
[ * ]

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

**EXHIBIT 10.28**

**[ * ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

# SECOND AMENDMENT

**THIS SECOND AMENDMENT** (the "***2nd Amendment***") is made and entered into effective as of December 23, 2016 (the "***2nd Amendment Effective Date***") by and between **CYMABAY THERAPEUTICS, INC.**, a Delaware corporation having a place of business at 7999 Gateway Blvd., Suite 130, Newark, CA 94560 USA ("***CymaBay***"), and **DIATEX, INC.**, a corporation organized under the laws of Texas with a place of business at 105 Elm Spring Lane, San Antonio, TX 78231 ("***DiaTex***"). CymaBay and DiaTex may be referred to herein individually as a "Party", and collectively as the "Parties."

## RECITALS

**WHEREAS**, CymaBay (through its prior name, Metabolex, Inc.) and DiaTex are parties to that certain License and Development Agreement, dated as of June 30, 1998, which the parties have amended by that certain First Amendment dated April 15, 1999 (collectively, the "**License Agreement**");

**WHEREAS**, the Parties desire to amend the License Agreement as provided herein;

**NOW, THEREFORE**, based on the premises and the mutual covenants and obligations set forth below, and intending to be bound hereby, the Parties agree as follows:

**1.** Section 5.2 is hereby amended as follows:

The phrase [ * ], is hereby amended to read in its entirety as follows:

[ * ]

**2.** Section 7.5 is hereby amended to read in its entirety as follows:

**"7.5 Infringement of DiaTex Patents.** If either Party becomes aware that a Third Party is infringing any rights in the DiaTex Patents, such Party shall give written notice to the other Party describing in detail the nature of such infringement. Metabolex (or its Sublicensee) shall have the initial right, but not the obligation, to enforce the DiaTex Patents against such Third Party infringer. If it is reasonably needed for DiaTex to be a party to any such enforcement action by Metabolex, for Metabolex to be able to bring such action, DiaTex agrees to join any such action as a party plaintiff at Metabolex's request, and Metabolex shall pay for any reasonable out-of-pocket expenses of DiaTex directly relating to such joinder. Metabolex shall in any event control all aspects of any such action it brings, notwithstanding that DiaTex joins in such action as a plaintiff plaintiff per the foregoing. Each Party agrees to provide the other Party (or its Sublicensee) all reasonable assistance in such enforcement at the requesting Party's sole expense. Any damages or other recovery, whether by settlement or otherwise, from an action hereunder to enforce DiaTex Patents shall first be applied pro rata to each Party to pay the costs and expenses of litigation in such action, and any remaining amount shall be paid to Metabolex and deemed to be Net Sales for purposes of royalty obligations to DiaTex hereunder."

**3.** Section 7.6 is hereby amended to read in its entirety as follows:

**"7.6 Infringement of Joint Patents.** If either Party becomes aware that a Third Party is infringing any Joint Patents or other Patent rights in the Joint Technology, such Party shall give written notice to the other Party describing in detail the nature of such infringement. Metabolex shall have the sole and exclusive right, at its expense and reasonable discretion, to enforce such Patents against any Third Party infringers. DiaTex agrees to provide Metabolex all reasonable assistance in such enforcement at Metabolex's sole expense. Such assistance shall include (without limitation), if requested by Metabolex, to join as a party plaintiff any enforcement action brought by Metabolex, and Metabolex shall pay for any reasonable out-of-pocket expenses of DiaTex directly relating to such joinder. Any damages or other recovery, whether by settlement or otherwise, from an action hereunder to enforce such Patents shall first be applied pro rata to each Party to pay such Party's unreimbursed costs and expenses of litigation in such action. Any remaining amount shall be paid to and retained by Metabolex, and [ * ] of such retained amount shall be deemed to be Net Sales for purposes of royalty obligations to DiaTex hereunder."

**4.** Section 10.2 is hereby amended to add the following sentence at the end of the Section:

"DiaTex hereby covenants that (a) if DiaTex provides notice to Metabolex of any breach of this Agreement pursuant to this Section 10.2, DiaTex will simultaneously provide written notice of such breach to any sublicensee of Metabolex, at the addresses specified by Metabolex; and, (b) if Metabolex fails to cure such breach within the time period set forth above, then any such sublicensee will have [ * ] days after the end of such period to cure such breach on behalf of Metabolex, and DiaTex agrees to accept any such cure effected by such sublicensee on behalf of Metabolex within such [ * ] days time period as a timely cure by Metabolex."

**5.** Section 10.4 is hereby amended to add the following sentences at the end of the Section:

"DiaTex further covenants that if this Agreement is terminated for any reason (including but not limited to the reasons set forth in Sections 10.2 and 10.3 of the Agreement):

(a) DiaTex shall provide notice to each sublicensee of such termination; and

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

(b) if, within [ * ] days of the date a sublicensee receives notice of termination of the Agreement:

(i) such sublicensee notifies DiaTex in writing of its desire to become a direct licensee of DiaTex on the terms and conditions of this Agreement (but solely with respect to the scope of rights and obligations sublicensed by CymaBay to such sublicensee); and

(ii) such sublicensee pays to DiaTex all amounts which became due and payable by CymaBay under this Agreement but which were unpaid as of the date of termination of the Agreement, but only to the extent the payments relate to rights and territories sublicensed by CymaBay to such sublicense;

then DiaTex shall consent, and hereby does consent, to entering into a new license agreement directly with such sublicensee on the terms and conditions of this Agreement, insofar as they relate to a sublicense of rights under this Agreement from CymaBay to such sublicensee, so that such sublicensee, instead of CymaBay, is a direct licensee of DiaTex under the relevant DiaTex Technology and Joint Technology in the applicable territories covered by such sublicense."

**6.** The License Agreement, except as amended by this Amendment, shall remain in full force and effect in accordance with the provisions thereof.

**7.** This Amendment may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Amendment may be executed and transmitted by PDF or via facsimile with the same validity as if it were an ink-signed document.

*******

*[signature page follows]*

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

**IN WITNESS WHEREOF,** the Parties have executed this Amendment by their duly authorized representatives as of the Amendment Effective Date.

| **CYMABAY THERAPEUTICS, INC.** | | **DIATEX, INC.** | |
|---|---|---|---|
| By: | /s/ Harold Van Wart | By: | /s/ Michael A. Friedberg |
| Name: | Harold Van Wart | Name: | Michael A. Friedberg |
| Title: | President and CEO | Title: | President |

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

**Exhibit 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, 333-198289 and 333-202941) pertaining to the Metabolex, Inc. 2003 Equity Incentive Plan, and the CymaBay Therapeutics, Inc. 2013 Equity Incentive Plan,

of our report dated March 23, 2017, 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, 2016.

/S/ ERNST & YOUNG LLP

Redwood City, California
March 23, 2017

**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.

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, 2017

/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.

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, 2017

/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, 2016, 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, 2017.

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